US009504467B2

(12) **United States Patent**
Ostrovsky et al.

(10) **Patent No.: US 9,504,467 B2**
(45) **Date of Patent: Nov. 29, 2016**

(54) **LESS TRAUMATIC METHOD OF DELIVERY OF MESH-BASED DEVICES INTO HUMAN BODY**

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(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 518 days.

(21) Appl. No.: **12/978,140**

(22) Filed: **Dec. 23, 2010**

(65) **Prior Publication Data**

US 2011/0152914 A1 Jun. 23, 2011

Related U.S. Application Data

(60) Provisional application No. 61/289,898, filed on Dec. 23, 2009.

(51) **Int. Cl.**

A61F 2/00	(2006.01)
A61B 17/06	(2006.01)
A61B 17/04	(2006.01)
A61B 17/00	(2006.01)

(52) **U.S. Cl.**
CPC ***A61B 17/06109*** (2013.01); *A61B 17/0482* (2013.01); *A61B 2017/00805* (2013.01); *A61F 2/0045* (2013.01)

(58) **Field of Classification Search**
CPC A61B 17/06109; A61B 2017/00805; A61B 17/0482; A61F 2/2481; A61F 2/0045
USPC 606/193, 151, 139; 600/37; 604/273
See application file for complete search history.

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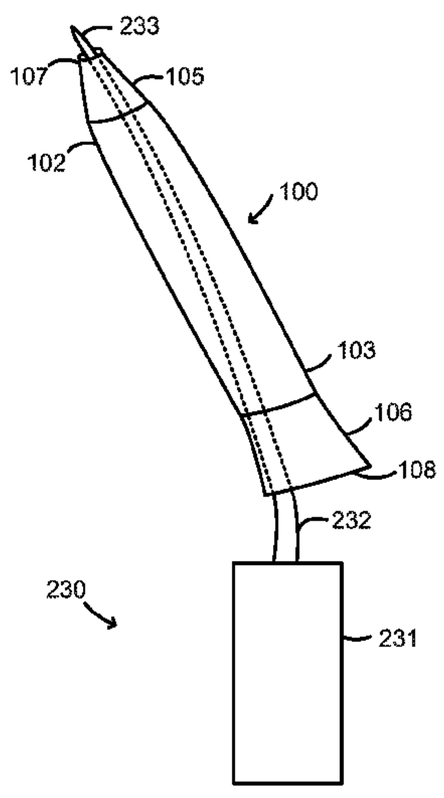
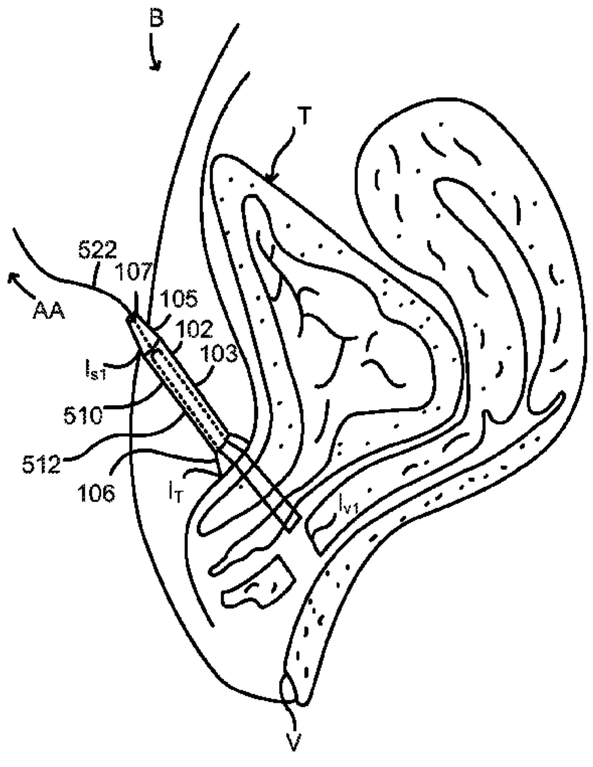
(57) **ABSTRACT**

In some embodiments, a method includes extending a dilator into a body of a patient in a first direction such that a distal end portion of the dilator extends from the body. The dilator defines a lumen therethrough. At least a portion of the dilator is disposed within the body when the distal end portion extends from the body. At least a portion of an implant is passed through the lumen defined by the dilator. The dilator is removed from the body by moving the dilator in the first direction.

16 Claims, 15 Drawing Sheets





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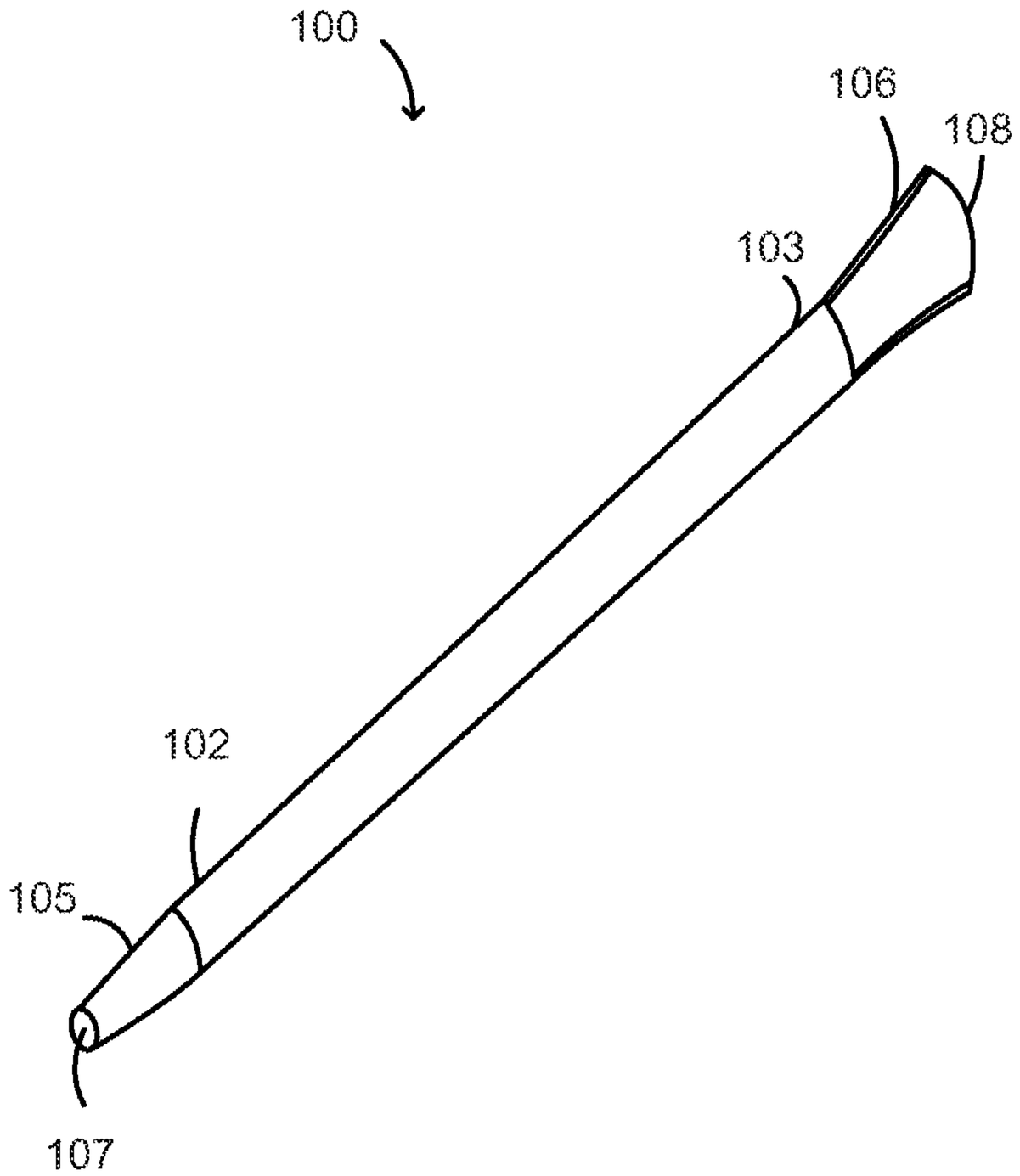


FIG. 1

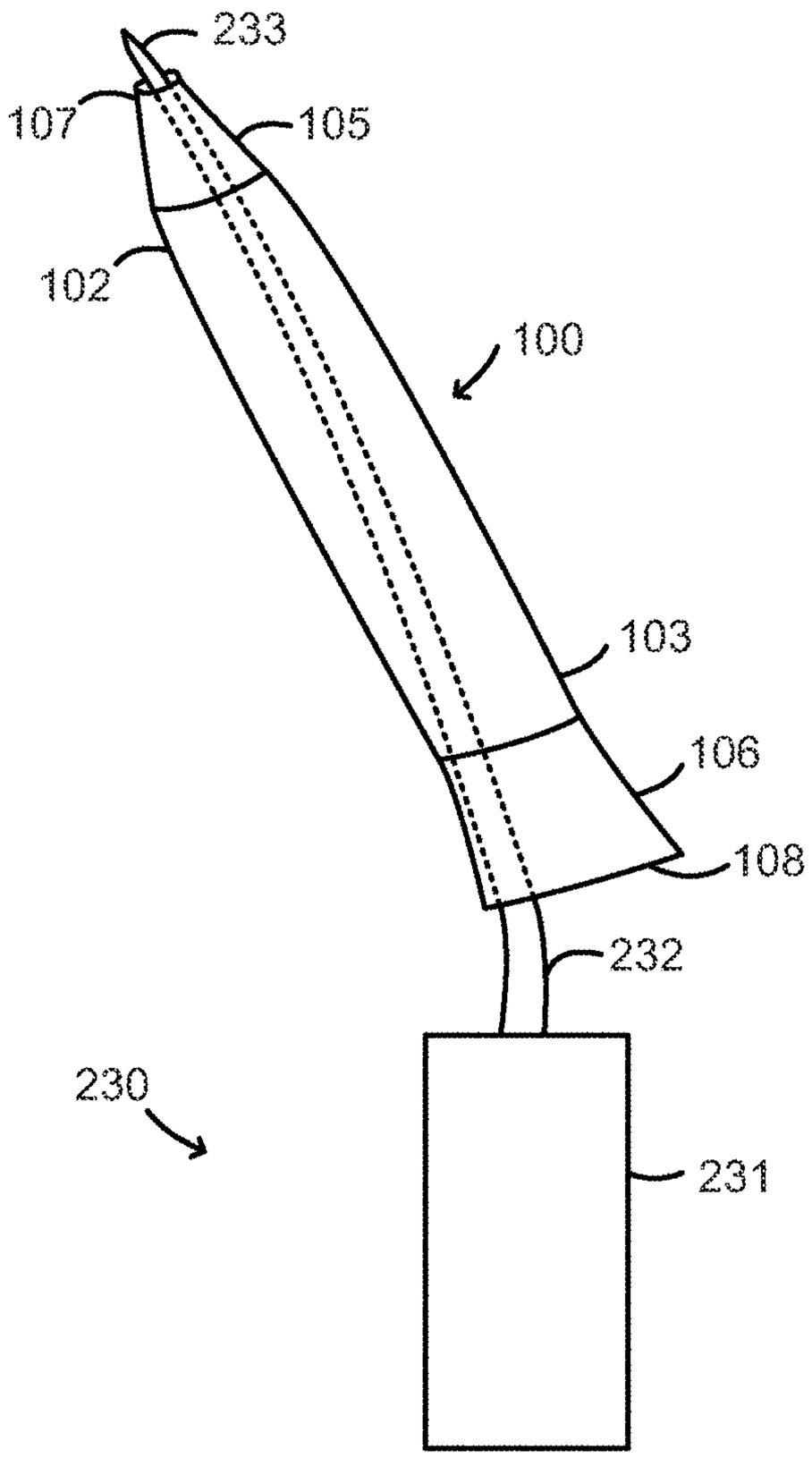


FIG. 2

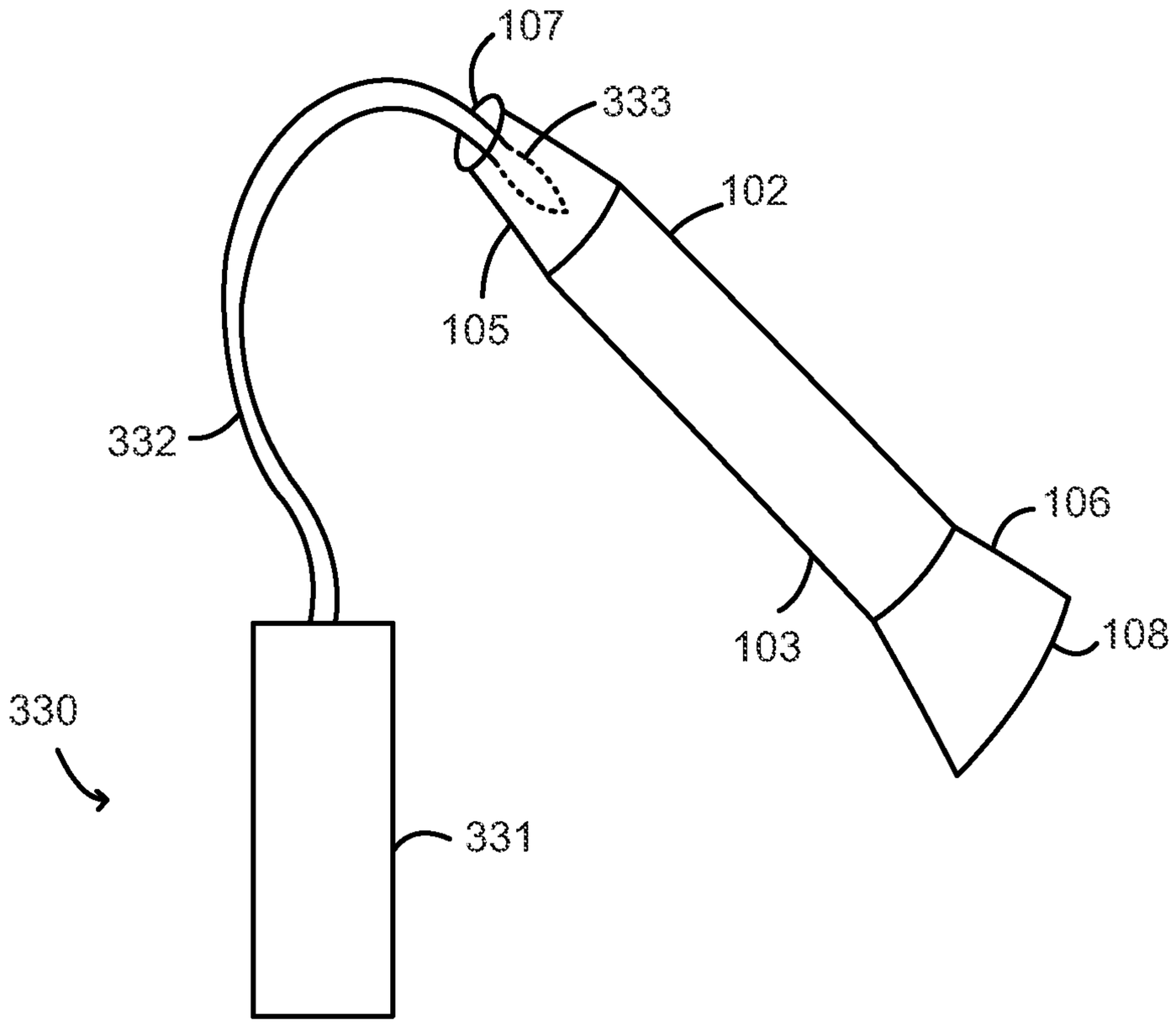


FIG. 3

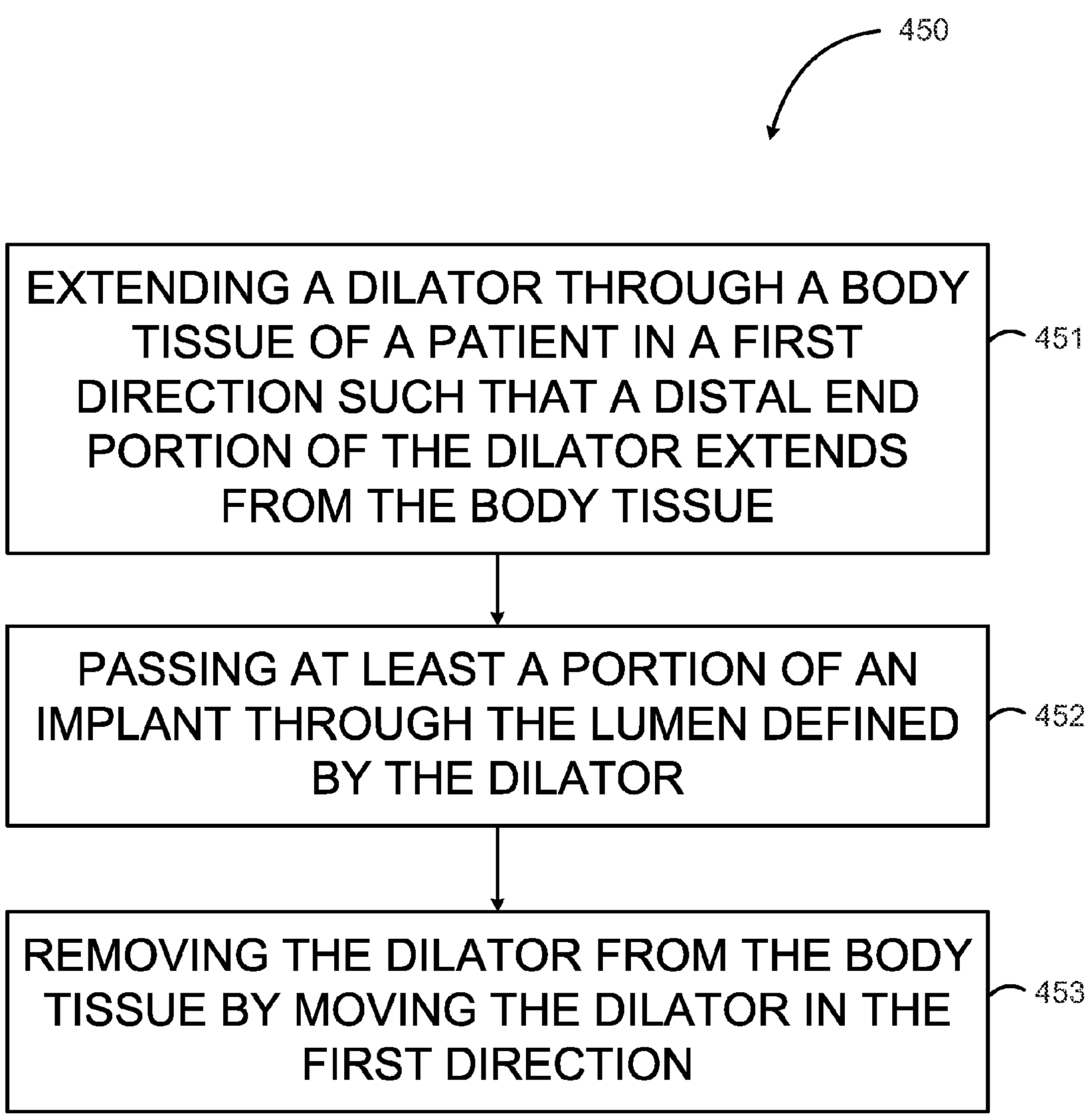

450
EXTENDING A DILATOR THROUGH A BODY TISSUE OF A PATIENT IN A FIRST DIRECTION SUCH THAT A DISTAL END PORTION OF THE DILATOR EXTENDS FROM THE BODY TISSUE
451
PASSING AT LEAST A PORTION OF AN IMPLANT THROUGH THE LUMEN DEFINED BY THE DILATOR
452
REMOVING THE DILATOR FROM THE BODY TISSUE BY MOVING THE DILATOR IN THE FIRST DIRECTION
453

FIG. 4

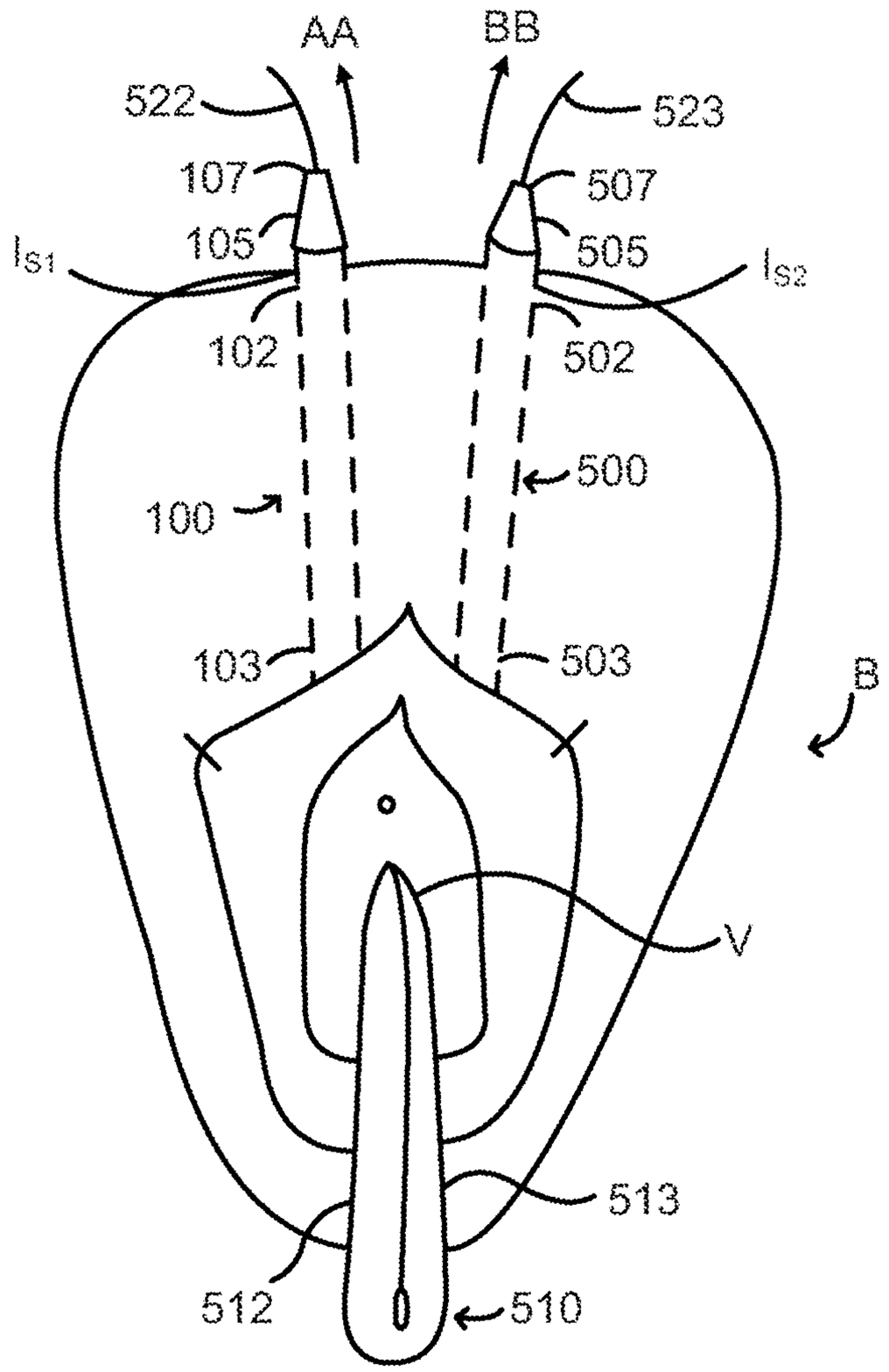

AA
BB
522
523
107
507
105
505
I_{S1}
I_{S2}
102
502
500
100
103
503
B
V
513
512
510

FIG. 5

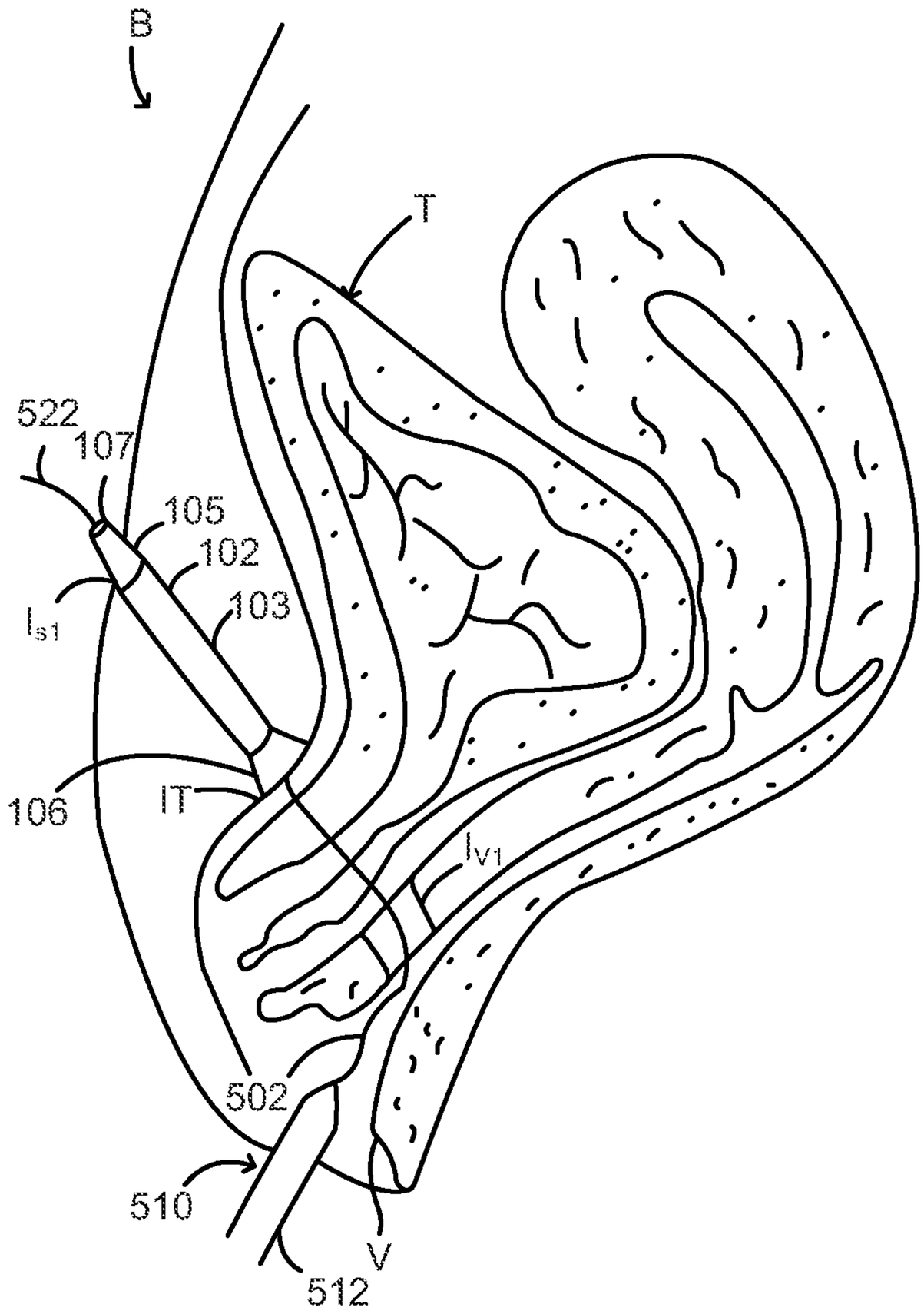


FIG. 6

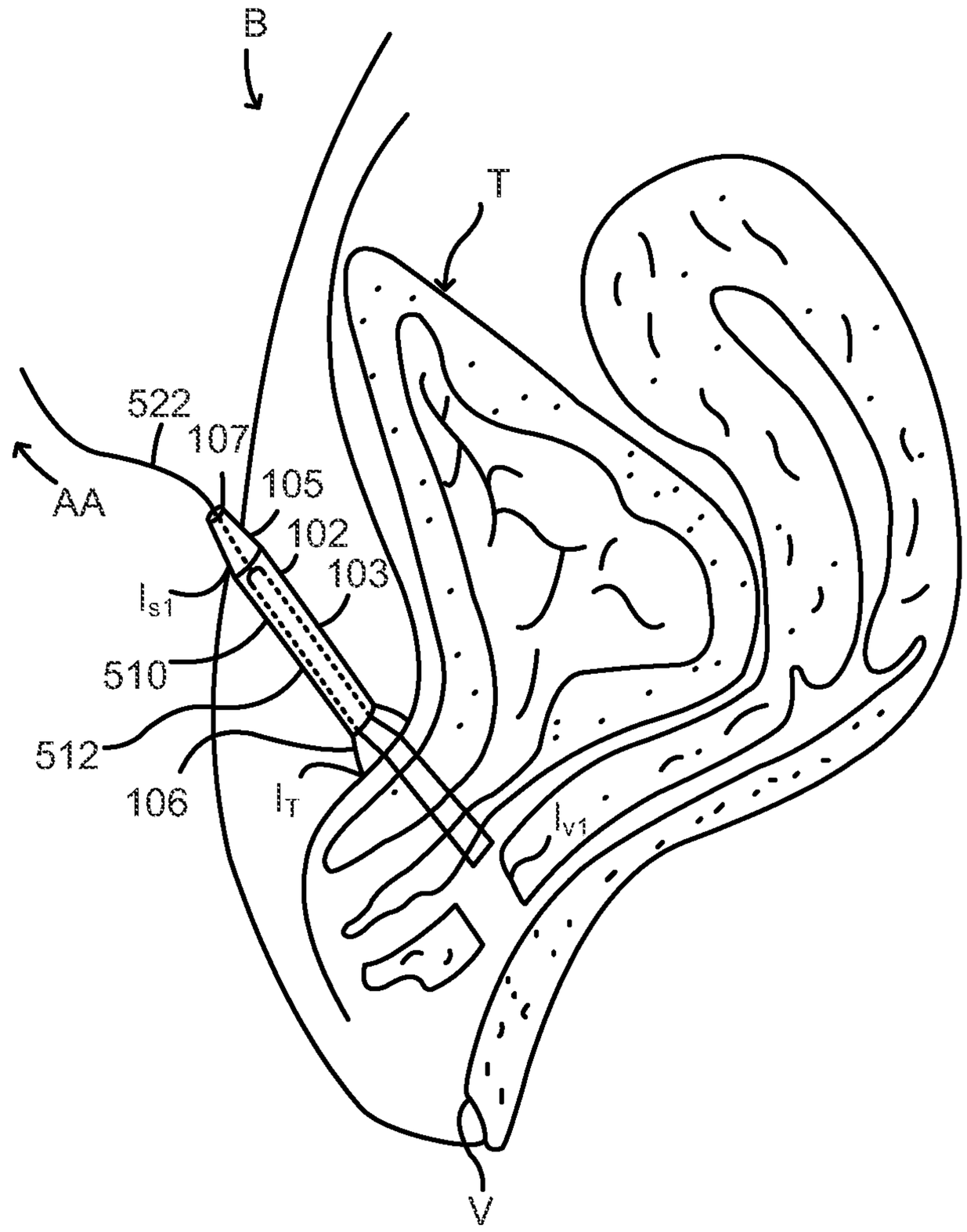


FIG. 7

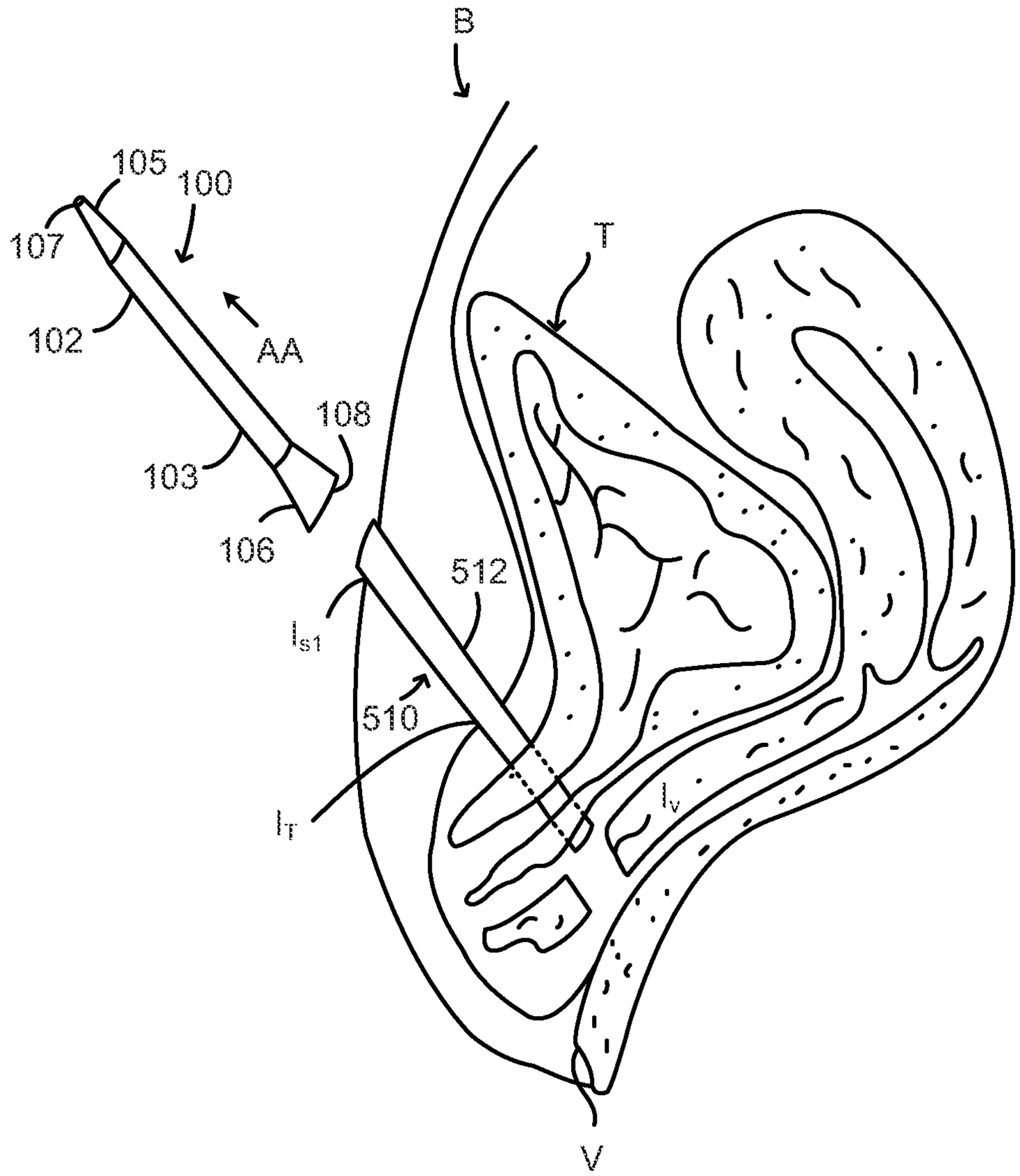
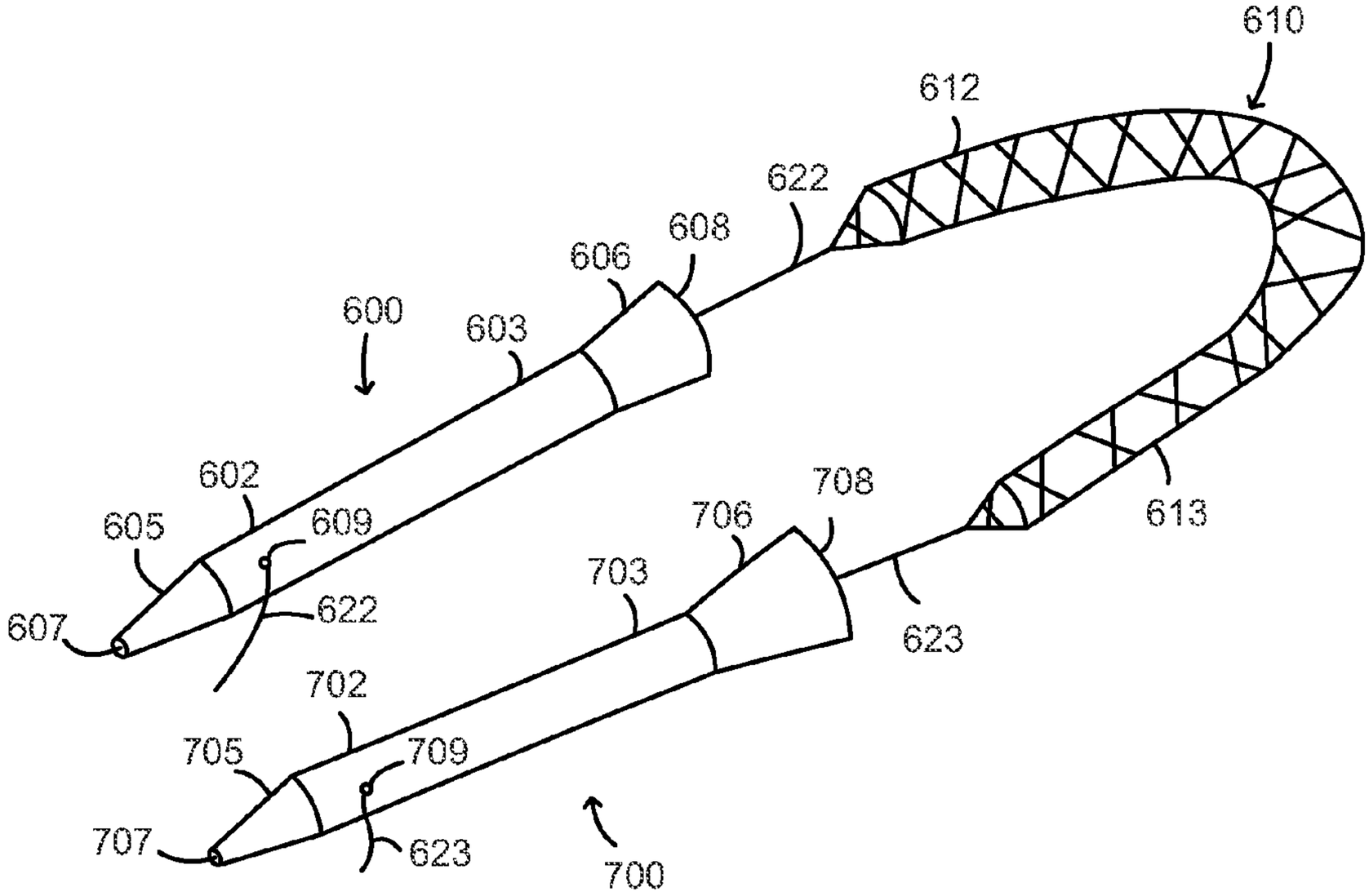


FIG. 8


610
612
622
608
606
600
603
602
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607
622
708
706
703
623
613
702
705
709
707
623
700

FIG. 9

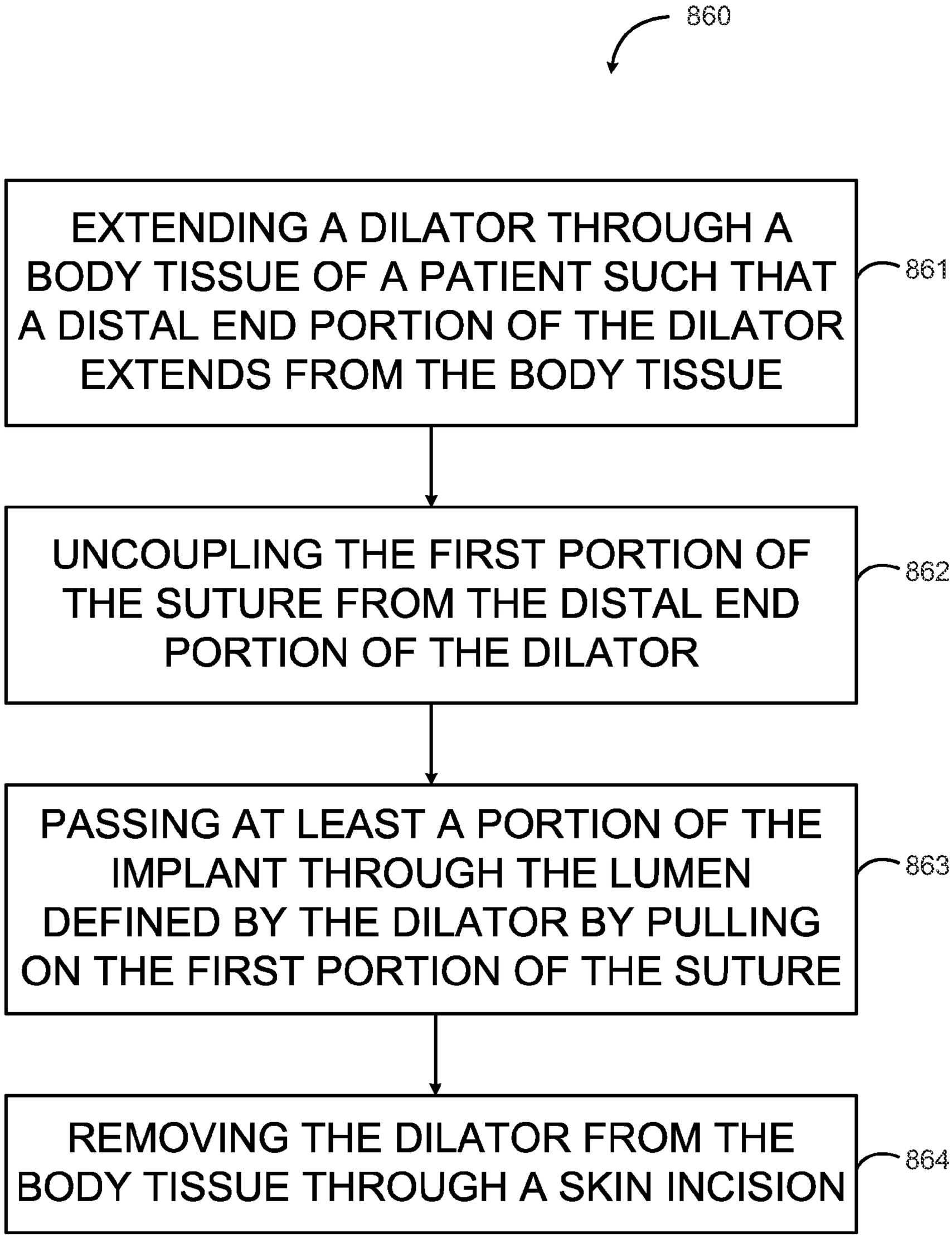
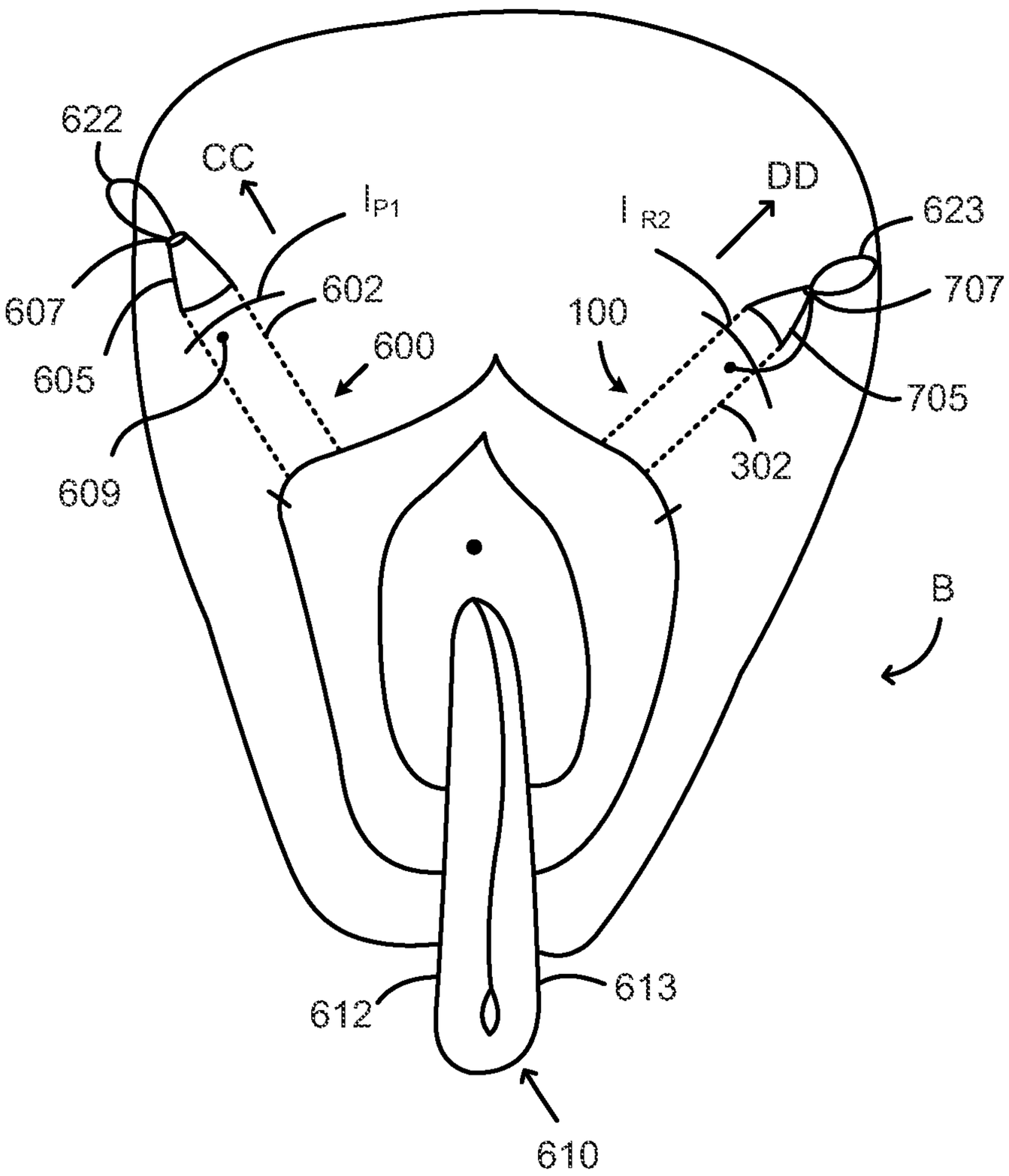

860
EXTENDING A DILATOR THROUGH A BODY TISSUE OF A PATIENT SUCH THAT A DISTAL END PORTION OF THE DILATOR EXTENDS FROM THE BODY TISSUE
861
UNCOUPLING THE FIRST PORTION OF THE SUTURE FROM THE DISTAL END PORTION OF THE DILATOR
862
PASSING AT LEAST A PORTION OF THE IMPLANT THROUGH THE LUMEN DEFINED BY THE DILATOR BY PULLING ON THE FIRST PORTION OF THE SUTURE
863
REMOVING THE DILATOR FROM THE BODY TISSUE THROUGH A SKIN INCISION
864

FIG. 10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CC
I_{P1}
I_{R2}
DD
623
607
602
707
100
600
605
705
609
302
B
612
613
610

FIG. 11

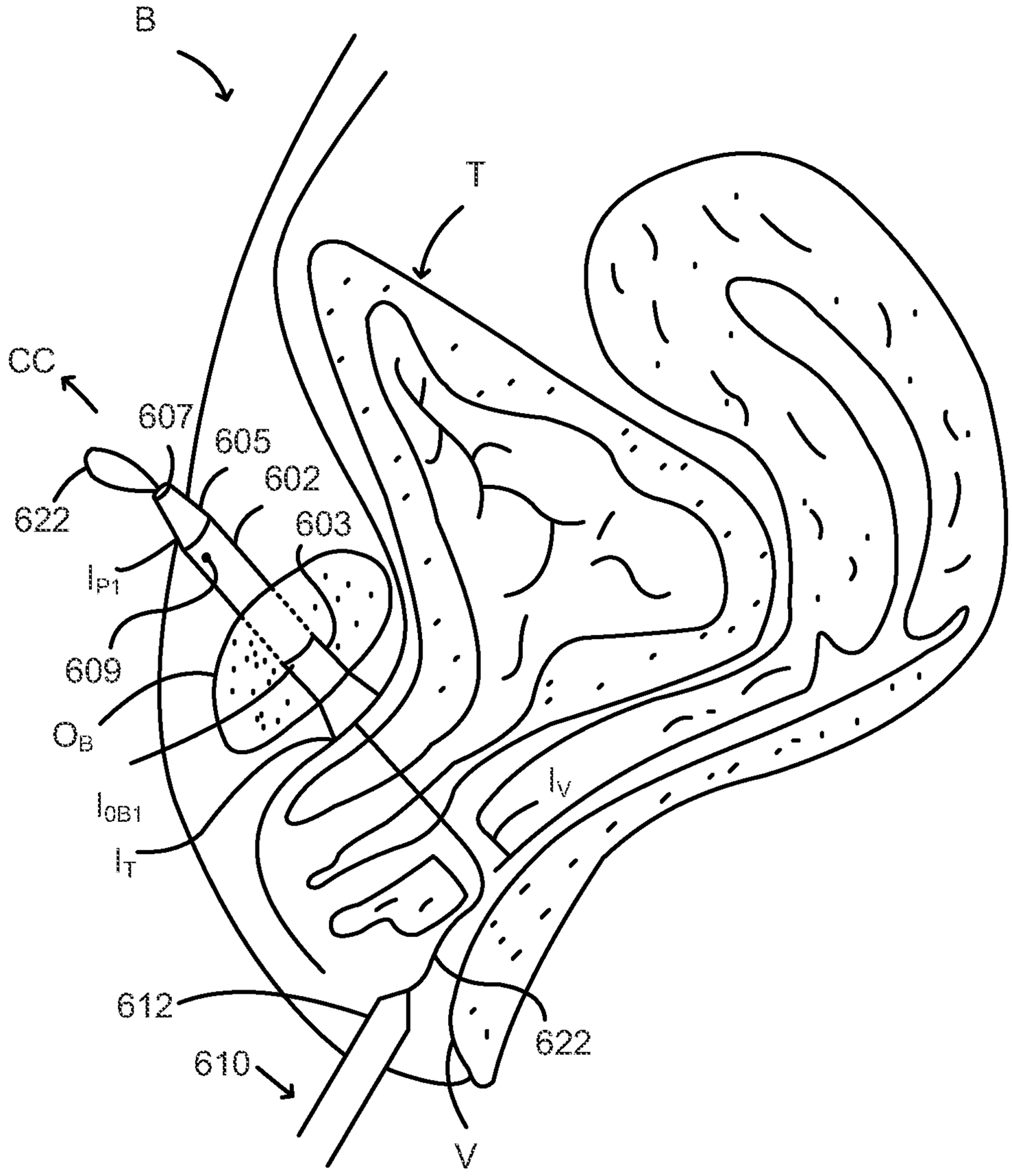

FIG. 12

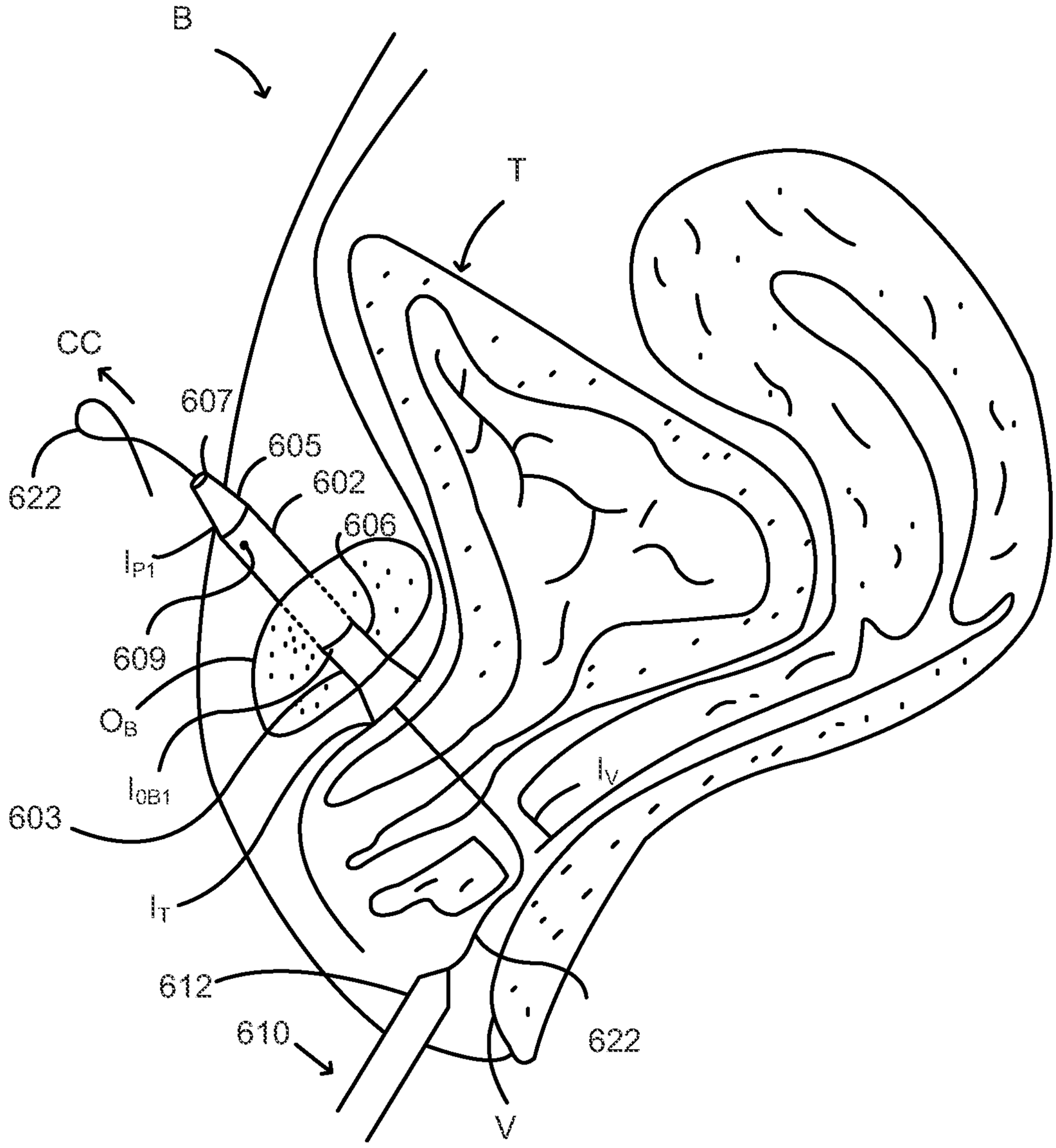

FIG. 13

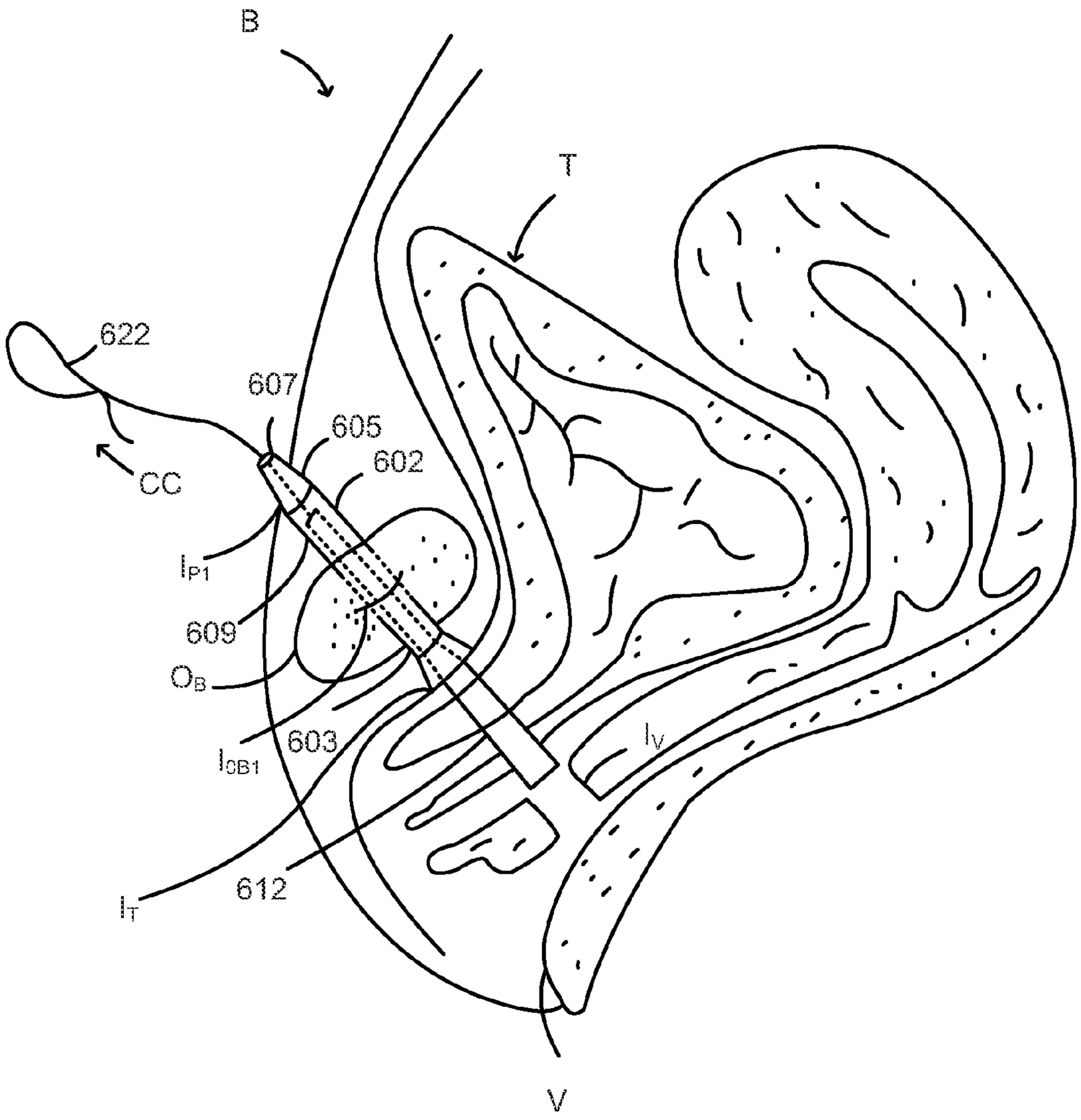

FIG. 14

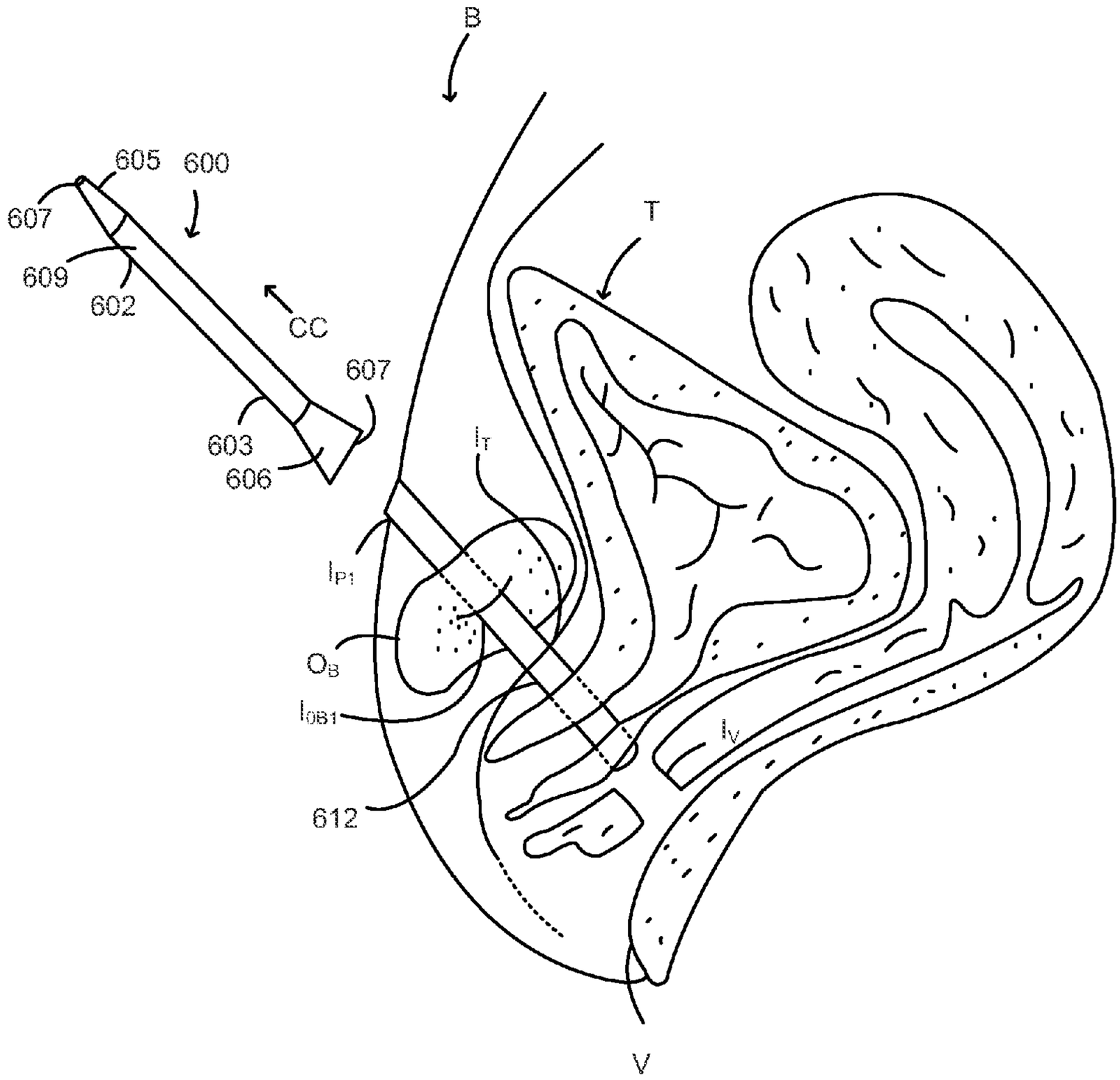

FIG. 15

LESS TRAUMATIC METHOD OF DELIVERY OF MESH-BASED DEVICES INTO HUMAN BODY

RELATED APPLICATION

This application claims priority to and the benefit of U.S. Provisional Patent Application Ser. No. 61/289,898, filed on Dec. 23, 2009, entitled, "Less Traumatic Method of Delivery of Mesh-Based Devices Into Human Body," which is incorporated herein by reference in its entirety.

BACKGROUND

The disclosed invention relates generally to medical devices and more particularly to implants and less traumatic methods for delivering implants within a pelvic region of a patient to treat various pelvic dysfunctions.

A variety of medical procedures are performed to treat various female pelvic dysfunctions, including procedures to treat urinary incontinence, and correcting various prolapse conditions such as uterine prolapse, cystoceles, rectoceles, and vaginal vault prolapse.

Women often experience vaginal prolapses due to age or other factors. For example, women may experience a cystocele, a rectocele and/or a hysterocele. A cystocele occurs when the bladder bulges into the vagina, and a rectocele occurs when the rectum bulges into the vagina. A hysterocele occurs when the uterus descends into the vagina. An enterocele small bowel prolapse) can also occur, when the small bowel pushes through the upper wall of the vagina. It is relatively common for a hysterocele and cystocele or hysterocele and rectocele, or other combinations thereof to occur at the same time. It is also common for different types of prolapse to occur in relatively quick succession.

Treatment has included suturing procedures or the use of implants for support or suspension. A hysterocele is often treated with a hysterectomy followed by a vaginal vault suspension. Various devices and procedures are used to deliver and secure pelvic implants within a variety of different anatomical structures within a pelvic region. Implants can be delivered to a pelvic region through one or more vaginal incisions, and/or through exterior incisions in the patient.

Known methods of delivering or implanting implants, such as slings, within the body include the use sleeves. In such known methods, a sleeve is disposed about the implant during insertion such that the sleeve and the implant are inserted within a bodily tissue. The sleeve, with the implant inside, is inserted through a bodily tissue. Once the implant is, for example, in a desired positioned within the bodily tissue, the sleeve can be removed from the body leaving the implant disposed within the bodily tissue. The sleeve protects the tissue from abrasion by the implant during delivery and adjustment, and protects the implant from over-stretching during delivery. The use of such known sleeves during implantation, however, can result in trauma to the bodily tissue through which the sleeve and implant have been inserted. More specifically, the sleeve adds bulk to the implant, and is typically stiffer than the implant, requiring larger incisions needed and/or holes created within the bodily tissue (for example, double the size). Undesirably large forces may also be required to pull the sleeved implant through a bodily tissue.

Thus, a need exists for a medical device that reduces trauma to the bodily tissue during insertion of an implant, i.e. by reducing the required size of the incision and/or the hole through the tissue. Also, a need exists for a medical device that reduces the force required to move the device through the bodily tissue.

SUMMARY

In some embodiments, a method includes extending a dilator into a body of a patient in a first direction such that a distal end portion of the dilator extends from the body. The dilator defines a lumen therethrough. At least a portion of the dilator is disposed within the body when the distal end portion extends from the body. At least a portion of an implant is passed through the lumen defined by the dilator. The dilator is removed from the body by moving the dilator in the first direction.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** is a schematic illustration of a dilator according to an embodiment.

FIG. **2** is a schematic illustration of a delivery needle coupled to the dilator in FIG. **1** according to an embodiment.

FIG. **3** is a schematic illustration of a delivery needle coupled to the dilator in FIG. **1** according to another embodiment.

FIG. **4** is a flow chart of a method of inserting an implant into a body using the dilator in FIG. **1** according to an embodiment.

FIGS. **5-8** are schematic illustrations showing a method of inserting the implant into the body using the dilator in FIG. **1**.

FIG. **9** is a schematic illustration of a dilator assembly according to an embodiment.

FIG. **10** is a flow chart of a method of inserting an implant into a body using the dilator assembly in FIG. **9** according to another embodiment.

FIGS. **11-15** are schematic illustrations showing a method of inserting the implant into the body using the dilator assembly in FIG. **9**.

DETAILED DESCRIPTION

The devices and methods described herein are generally directed to implants (e.g., slings for treatment of incontinence, such as by bladder neck suspension, posterior support implants, anterior support implants, and total pelvic floor repair implants) and the delivery and placement of such implants within a pelvic region of a patient using one or more dilators. An implant can be placed into the pelvic space of a patient and secured at one or more locations within the pelvic space to treat many different female pelvic floor dysfunctions.

The insertion device (i.e., the one or more dilators) is configured to place, deposit, or otherwise insert an implant (e.g., a sling) into one or more bodily tissues of a patient. The implant is configured to suspend or support a bodily tissue or organ when the implant is retained within the patient through tissue ingrowth and/or temporary suturing. For example, in one embodiment, the insertion device can place the implant under the bladder neck through the both obturator externus muscles and further through corresponding skin incisions for incontinence treatment.

As used in this specification, unless otherwise apparent from the context, the words "proximal" and "distal" refer to the direction closer to and further away from, respectively, an operator (e.g., surgeon, physician, nurse, technician, etc) who would use an insertion device during a procedure. For

example, the end of an insertion device first to contact the patient's body would be the distal end, while the opposite end of the insertion device (e.g., the end of the insertion device being operated by the operator) would be the proximal end of the insertion device. Similarly, the end of a insertion device implanted the furthest within the patient's body would be the distal end, while the opposite end of the insertion device (e.g., the end of the insertion device that is inserted the least amount within the body or the end of the insertion device that is disposed outside of the body) would be the proximal end.

FIG. **1** is a schematic illustration of a dilator **100** configured to be inserted within a body of a patient and to deliver an implant within the body. The dilator **100**, which can be, for example, a tube, includes a proximal end portion **103** and a distal end portion **102**. Additionally, the dilator **100** defines a distal opening **107**, a proximal opening **108** and a lumen (not identified) extending therethrough. The distal opening **107** is in fluid communication with the proximal opening **108** via the lumen. The lumen is configured to receive at least a portion of an implant (not illustrated) via the distal opening **107** and/or the proximal opening **108**, as described herein. The lumen is also configured to receive at least a portion of a delivery needle (not illustrated) via the distal opening **107** and/or the proximal opening **108**, as described herein.

The distal end portion **102** of the dilator **100** is configured to be inserted into a bodily tissue through an incision. Such a bodily tissue can be, for example, a vaginal tissue, an obturator membrane, a supra-pubic tissue, a retro-pubic tissue and/or the like. The distal end portion **102** of the dilator **100** may include a tapered tip **105**. The tapered tip **105** is configured to allow the dilator **100** to advance through the bodily tissue more easily. Said another way, the tapered tip **105** facilitates a smooth insertion of the dilator **100** into the bodily tissue. The tapered tip **105** can be tapered at any suitable angle (or rate) to reduce tissue resistance during insertion.

The proximal end portion **103** of the dilator **100** includes an enlarged portion **106**. The enlarged portion **106**, which may have, for example, a cone shape, is configured to operate as a funnel for the dilator **100**. For example, the enlarged portion **106** can receive, via the proximal opening **108**, a portion of an implant having a lateral dimension larger than a diameter of the lumen. The enlarged portion **106** can facilitate advancing the implant through the lumen by enabling the implant to gradually contract to a dimension sufficient to fit through the lumen without the exertion of undue force on the dilator **100** and/or the implant. In some instances, when the proximal end portion **103** of the dilator **100** is extended through a bodily tissue, the enlarged portion **106** provides a surgeon (or other doctor) a larger area with which to perform a procedure. The enlarged portion **106** can increase at any suitable angle (or rate). Although the enlarged portion **106** is illustrated and described above as having a cone shape (i.e., a circular funnel shape), in other embodiments, the enlarged portion **106** can have any suitable shape and/or size. For example, in some embodiments, the enlarged portion **106** can have a flat funnel shape. In some embodiments, however, the dilator **106** does not include an enlarged portion **106**.

In use, the dilator **100** is configured to engage a delivery needle (e.g., delivery needle **230** or **330** shown in FIGS. **2** and **3**, respectively) prior to insertion into the body. The delivery needle is configured to either push or pull the dilator **100** through an incision and into the body, as described in more detail herein. In one example, the delivery needle can push the dilator **100** through a vaginal incision. The delivery needle can further push the distal end portion **102** of the dilator **100** through the pelvic region of the body (including, for example, the retropubic space or the obturator foramens) and out of a skin incision, e.g. suprapubic or perineal. In such an example, the dilator **100** is positioned within the body such that the proximal end portion **103** is disposed flush with the first layer of tissue in which the implant is to be anchored and the distal end portion **102** is disposed through the skin incision, extending from the body.

Once the dilator **100** is positioned within the body, the delivery needle is disengaged from the dilator **100** and a portion of an implant can be advanced through the lumen of the dilator **100**. The implant can be, for example, a mesh sling or a mesh tape having a flat configuration or a rolled configuration. In some embodiments, a portion of the implant can be pushed through the dilator **100** in a distal direction via a pusher. In some embodiments, a portion of the implant can be coupled to a suture such that the suture is passed distally through the lumen and out of the distal opening **107** of the dilator **100**. The surgeon, for example, can then pull the suture and guide the implant into the lumen of the dilator **100** via the suture.

Once a suitable portion of the implant is disposed within the dilator **100**, the implant can be adjusted and/or tensioned. Since the length of the dilator **100** is sufficient to extend through body tissue from an entrance incision (e.g., in tissue in the pelvic region, accessed via a vaginal incision) to an exit incision (e.g. the supra-pubic incision), the implant can be inserted and positioned within the body within the dilator **100** without contacting any portion of the body other than the desired tissue or organ the implant is configured to support, as described in more detail herein. It should be understood that, although the procedure described above refers to only one dilator **100**, insertion of an implant, such as a sling, often involves the use of two dilators (see, for example, FIG. **9**). For example, the dilator **100** can be used to implant a right portion of a sling and another dilator can be used to implant a left portion of the sling such that a body portion of the sling is disposed beneath and supports a bladder neck. In such an example, the dilator **100** extends through tissue in the retropubic region and a right supra-pubic incision, while the other dilator extends through tissue in the retropubic region and a left supra-pubic incision. Thus, an adjustment or tensioning of the sling can include adjusting the right portion of the sling relative to the left portion of the sling such that the body portion of the sling is properly tensioned to support the bladder neck.

The dilator **100** can be removed from the body after the implant is positioned within the body (albeit within the dilator **100**, which is within the body). The implant remains within the body and now contacts the bodily tissue between the supra-pubic incision site and the internal tissue incision. The vaginal incision can then be closed via suturing and/or the like. The portion of the implant extending from the external (e.g. supra-pubic) incision can be trimmed off, and the external incision can also be closed (with the portion of the implant disposed therein) via suturing and/or the like. In some embodiments, the dilator **100** can be removed from the body by moving the dilator **100** in the distal direction (i.e., the same direction as the insertion). In this manner, the proximal end portion **103** of the dilator **100** exits the body via the skin incision.

The dilator **100** can have any suitable shape and/or size. The dilator **100** can be constructed of any suitable, biocompatible material configured to be disposed within the body. For example, the dilator **100** can be constructed of a sub-

stantially rigid material, such as a stainless steel. In some embodiments, the dilator **100** can be constructed of a polymer. The dilator **100** can be formed, for example, by molding, extruding, casting, sintering, forging, machining, or other known methods of manufacturing, such medical devices.

The dilator **100** can have a substantially smooth and/or continuous outer surface to prevent or reduce friction produced between the dilator **100** and the bodily tissue when the dilator **100** contacts the bodily tissue during insertion. As friction between the dilator **100** and the bodily tissue decreases, the amount of force required to insert or move the dilator **100** through the bodily tissue decreases. Thus, the likelihood of damaging the bodily tissue during insertion also decreases.

In some embodiments, the distal end portion **102** of the dilator **100** can include an aperture (not illustrated in the embodiment of FIG. **11**, but illustrated, for example in the embodiment of FIG. **9**) through which a suture can extend. For example, as described above, the implant can be coupled to a suture such that the suture is passed through the dilator **100** and used to pull or guide the implant through the dilator **100**. In this embodiment, an end of the suture can be laced through the aperture and, for example, tied to the distal end portion **102** of the dilator **100** such that the suture is releasably coupled to the dilator **100** before insertion. In this manner, the dilator **100** is inserted within the body along with the suture. When the surgeon, for example, is ready to move the implant into the dilator **100**, the suture can be decoupled untied), removed from the aperture and pulled in the same manner described above. In some embodiments, however, the suture can be fixedly coupled within the aperture and/or a distal end potion **102** of the dilator **100**.

FIG. **2** is schematic illustration of the dilator **100** coupled to a delivery needle **230** prior to insertion into a body. The delivery needle **230** is configured to push the dilator **100** through the body. The method of inserting the dilator **100** via the delivery needle **230**, as disclosed below, is herein referred to as the "push" method. The delivery needle **230** includes a handle **231** and a needle **232** with a tip **233**. The needle **232**, which has a slight curvature along its length, is coupled to the handle **231**.

When the delivery needle **230** is coupled to the dilator **100**, the needle **232** is disposed within the lumen defined by the dilator **100** such that the tip **233** of the needle **232** extends from the distal opening **107** of the dilator **100**. In some embodiments, the tip **233** and/or another portion of the needle **232** can form an interference fit with the dilator **100** when the needle **232** is disposed within the distal opening **107**. In this manner, the dilator **100** can be restricted from moving or uncoupling from the delivery needle **230** during insertion. On other embodiments, however, the needle **232** can be coupled to the dilator **100** in any other suitable manner.

In use, the delivery needle **230** is coupled to the dilator **100** in the manner described above, and inserted into the body, for example, via a vaginal incision. The delivery needle **230** can be operated, for example, by a surgeon. The delivery needle **230** is pushed through the body toward, for example, a supra-pubic incision, such that the dilator **100** is pushed through body tissue toward the supra-pubic incision. In some embodiments, the delivery needle **230** can be pushed through the body toward, for example, a retro-pubic incision, a perineum incision and/or the like. Additionally, in some embodiments, pushing the delivery needle **230** through the body includes pushing the delivery needle **230** and a portion of the dilator **100** through an obturator membrane.

The advancement of the delivery needle **230** through the body is halted after the tip **233** of the delivery needle **230** reaches the supra-pubic incision (or other desired incision) and the distal end portion **102** of the dilator **100** extends from the body through the supra-pubic incision (or other desired incision), once the proximal opening **108** of the dilator is approximately flush with the body tissue into which the dilator **100** has been inserted. The delivery needle **230** can then be uncoupled from the dilator **100** and removed from the body. The delivery needle **230** is removed by moving (or pulling) the needle **232** in the opposite direction from which it was pushed through the body. In this manner, the delivery needle **230** is removed from the vaginal incision (i.e., the same incision through which it was inserted). The dilator **100** remains within the body.

FIG. **3** is a schematic illustration of the dilator **100** coupled to a delivery needle **330** during insertion into a body. The delivery needle **330** is configured to pull the dilator **100** through the body tissue. Thus, as will be described in more detail herein, the delivery needle **330** is configured to be inserted within the body before the dilator **100**. The method of inserting the dilator **100** via the delivery needle **330**, as disclosed below, is herein referred to as the "pull" method. The delivery needle **330** includes a handle **331** and a needle **332** with a tip **333**. The needle **332**, which has a C-shaped curvature, is coupled to the handle **331**. The needle **332** can have any suitable shape and/or size. For example, in some embodiments, the needle **332** can have the same shape and/or size as the needle **232** of the delivery needle **230** shown in FIG. **2**.

When the delivery needle **330** is coupled to the dilator **100**, the tip **333** of the needle **332** is disposed within, or adjacent to, the distal opening **107** defined by the dilator **100**. More specifically, as shown in FIG. **3**, the tip **333** of the needle **332** extends within the lumen of the dilator **100**. In some embodiments, the tip **333** and/or another portion of the needle **332** can form an interference fit with the dilator **100** when the needle **332** is disposed within the distal opening **107**. In this manner, the dilator **100** can be restricted from moving or uncoupling from the delivery needle **330** during insertion. In some embodiments, the tip **333** and/or another portion of the needle **332** can define a groove or recess configured to receive and/or couple to the distal end portion **102** of the dilator **100**.

In use, the delivery needle **330** is inserted into the body via an exit incision, such as, for example, a supra-pubic incision. The exit incision is the incision from which the distal end portion **102** of the dilator **100** will extend once placed, as discussed in more detail herein. In some embodiments, the exit incision can be, for example, a retro-pubic incision, a perineum incision and/or the like. The delivery needle **330**, which can be operated, for example, by a surgeon, is pushed through the body tissue toward an entry point adjacent the tissue or organ to be engaged by the implant. Once the tip **333** of the needle **332** passes through the entry point and enters a region of the pelvic area where it can be accessed (e.g. via a vaginal incision), the delivery needle **330** is coupled to the dilator **100** in the manner described above. The delivery needle **330**, with the dilator **100**, is then retracted or pulled back into the body in the opposite direction from which it was inserted.

The delivery needle **330** continues to retract through the body, pulling the dilator **100**, until the distal end portion **102** of the dilator **100** extends from the body through the

supra-pubic incision. In some embodiments, pulling the delivery needle **330** through the body includes pulling the delivery needle **330** and a portion of the dilator **100** through an obturator membrane and out through a perineal incision. The delivery needle **330** can then be uncoupled from the dilator **100** and removed from the body. In some embodiments, however, the delivery needle **330** is removed from or disposed outside of the body when the delivery needle **330** is uncoupled from the dilator **100**. In embodiments where a portion of the delivery needle **330** (e.g., the tip **333**) is disposed within the body when the delivery needle **330** is uncoupled from the dilator **100**, the delivery needle **330** can be removed by moving (or pulling) the remainder of the needle **332** from the body in the same direction along which it pulled the dilator **100** through the body. In this manner, the delivery needle **330** is removed from the supra-pubic incision the same incision through which it was inserted). The dilator **100** remains within the body.

The needles **232** and/or **332** can be constructed from any suitable material and can have any suitable shape and/or size, as discussed briefly above. Similarly, the handles **231** and/or **331** can be any suitable handle. The needles **232** and/or **332** can be constructed of any suitable material and can have any suitable shape and/or size.

In some embodiments, the needle (e.g., needle **232** and/or needle **233**) can include a coupling member (not illustrated) configured to couple the needle to the dilator **100**. The coupling member, which can be disposed on the distal end of the needle, is configured to be disposed within the lumen of the dilator **100** when the needle is coupled to the dilator **100**. In some embodiments, the coupling member can be portion of the needle having an increased diameter such that the needle is coupled to the dilator **100** via friction. Said another way, the dilator **100** and the needle can form an interference fit via the coupling member, when the coupling member is disposed within the lumen of the dilator **100**. In some such embodiments, the coupling member can be remotely controlled such that the diameter of that portion of the needle can increase and/or decrease on command. The coupling member can be actuated, for example, by pulling a wire on a handle (e.g., handle **231** and/or **331**) of the needle, by pushing a button disposed on the handle, by squeezing a portion of the handle, and/or the like.

In some embodiments, the coupling member can include female threads configured to receive male threads disposed on the distal end portion **102** of the dilator **100**. In this manner, the needle (e.g., needle **232** and/or needle **233**) and the dilator **100** are releasably and threadedly coupled together.

FIG. **4** is a flow chart of a method **450** of inserting an implant **510** into a body B of a patient. The method illustrated in FIG. **4** is discussed with references FIGS. **5-8**, which are schematic illustrations of the implant **510** being inserted into the body B via dilators **100** and **500**. The term "implant" will be referred to herein as a "sling," unless otherwise specified. It should be understood, however, that the implant **510** can be any suitable implant including, but not limited to, a sling. For example, the implant **510** can be a mesh tape having a flat configuration or a rolled configuration. The method **450** includes extending a dilator through a body tissue of a patient in a first direction such that a distal end portion of the dilator extends from the body tissue, **451**. Referring to FIGS. **5** and **6**, the dilator **100** extends through the body B of the patient in a distal direction AA such that the distal end portion **102** of the dilator **100** extends from the body B. Similarly, the dilator **500** extends through the body B of the patient in a distal direction BB such that a distal end portion **502** of the dilator **500** extends from the body B. The dilator **500** has substantially the same structure and operation as dilator **100** and thus, will not be described in detail herein. Also, it should be understood that, during the procedures described herein, the dilator **500** performs the same steps or operations that dilator **100** performs. Therefore, when the dilator **100** is described as or referred to in performing a particular step or operation, it should be understood that dilator **500** is also involved in or performing that particular step or operation, unless otherwise specified.

The dilator **100** is inserted into the body B of the patient via a vaginal incision, I_V (shown in FIG. **6**). The dilator **500** is also inserted into the body B of the patient via the vaginal incision I_V. In this manner, there is only a single incision in the vaginal wall V through which both dilators **100** and **500** are inserted to access the tissue through which they will extend to the exterior of the body B, i.e. through incisions in the skin of body B. The incision I_V can be made at any suitable location along the vaginal wall V depending on the intended implantation site of the sling **510** within the pelvic region. For example, the vaginal incision I_V is shown in FIG. **6** as being located in the anterior vaginal wall V proximate the mid-urethra (i.e., the intended implantation location/site).

The distal end portion **102** of the dilator **100** extends from the body B of the patient via a first supra-pubic incision I_{S1}. Similarly, the distal end portion **502** of the dilator **500** extends from the body B of the patient via a second suprapubic incision I_{S2}. The first supra-pubic incision I_{S1} is located toward the right side of the body B and the second supra-pubic incision I_{S2} is located toward the left side of the body B relative to the perspective of the patient. In some embodiments, however, the supra-pubic incisions I_{S1} and I_{S2} can be made at any location in the supra-pubic region of the body B. In some embodiments, the location of the supra-pubic incisions I_{S1} and/or I_{S2} can depend, for example, on the intended implantation site of the sling **510** within the pelvic region.

The dilator **100** can be inserted into the body B using one of the methods described above with reference to FIGS. **2** and **3**. More particularly, the dilator **100** can be pushed into the body B (through body tissue) using, for example, the delivery needle **230** (i.e., the "push" method). Or, the dilator **100** can be pulled into the body B using, for example, the delivery needle **330** the "pull" method), in most instances, however, the "push" method is regularly used for procedures involving supra-pubic incisions. As such, the dilator **100** is inserted into the body B by being pushed through the vaginal incision I_V and further through the pelvic region (including, the tissue in the supra-pubic space), in distal direction AA, until the distal end portion **102** of the dilator **100** extends from the first supra-pubic incision I_{S1}. In some embodiments, the dilator **100** can be inserted into the body B in a manner different from the dilator **500**. For example, the dilator **100** can be inserted into the body B via the "push" method, and the dilator **500** can be inserted into the body B via the "pull" method. Regardless of the method used to insert the dilators **100** or **500**, the dilator **100** is moved through the body B in direction AA during insertion and dilator **500** is moved through the body B in direction BB during insertion.

When the dilator **100** is extended through the body B, as shown in FIGS. **5** and **6**, the proximal end portion **103** of the dilator **100** is disposed within at least the first layer of tissue T_1 (via a first tissue layer incision I_T) in which the sling **510** is to be anchored and a proximal-most end (not identified) of the dilator **100** is flush with that first layer of tissue T_1. In

some embodiments, however, the proximal-most end of the dilator **100** can be flush with the vaginal wall V (i.e., the vaginal tissue). The placement of the proximal-most end of the dilator **100** can facilitate a more accurate placement of the sling **510** at the desired implantation site within the body B. For example, the ability to tension and/or adjust the sling **510** with respect to the urethra (or another desired implantation site) may be restricted in instances where the proximal-most end(s) of the dilators **100** and/or **500** extend beyond the first layer of tissue T_1. In instances where the proximal-most end(s) of the dilators **100** and/or **500** are recessed within that first layer of tissue T_1, the tissue surrounding the first tissue layer incision I_T can close up around the dilator **100**. In some embodiments, however, the proximal-most end of the dilator **100** can be recessed within the first layer of tissue T_1 or can extend into the vagina through the vaginal incision h.

As shown in FIG. **5**, a first suture **522** is disposed within the lumen defined by the dilator **100**. The first suture **522** has a first portion (not identified), which extends from the distal opening **107** of the dilator **100**, and a second portion (not identified), which is coupled to a first arm **512** of the sling **510**. Similarly, a second suture **523** is disposed within the lumen defined by the dilator **500**. The second suture **523** has a first portion (not identified), which extends through the distal opening **507** of the dilator **500**, and a second portion (not identified), which is coupled to a second arm **513** of the sling **510**. As discussed in more detail herein, the sutures **522** and **523** are configured to facilitate the placement of the sling **510** within the body B. During this phase of the implantation procedure, however, the sling **510** may remain outside of the body B.

Returning to the flow chart shown in FIG. **4**, at least a portion of an implant can be passed through the lumen defined by the dilator, **452**. As shown in FIG. **7**, the first arm **512** of the sling **510** is passed or moved in distal direction AA through the lumen defined by the dilator **100**. More specifically, the first portion of the first suture **522** is moved in distal direction AA (i.e., away from the body B and/or the dilator **100**) such that the first arm **512** of the sling **510** is moved in the distal direction AA. The first suture **522** can continue to be moved or pulled in the distal direction AA until the first arm **512** of the sling **510** is in the desired position within the lumen defined by the dilator **100**. The desired position of the first arm **512** of the sling **510** within the lumen can, for example, correspond to the desired location of the sling **510** within the body B after implantation. Such a desired position can be achieved by, for example, adjusting and/or tensioning the first arm **512** of the sling **510** within the lumen relative to the second arm **513**. The first suture **522** is, therefore, configured to guide the first arm **512** of the sling **510** into the lumen defined by the dilator **100** and to facilitate its placement within the lumen.

As shown in FIG. **7**, the dilator **100** is configured to act a barrier between the first arm **512** of the sling **510** and the body B (including the body tissue through which the dilator is passed) when the first arm **512** is disposed within the lumen of the dilator **100**. Said another way, the dilator **100** substantially prevents the first arm **512** of the sling **510** from contacting body tissue (other than the organ it is intended to support) when the first arm **512** is disposed within the lumen of the dilator **100**. The first arm **512** of the sling **510** has a length sufficient to extend through body tissue from the vaginal incision I_V or the desired implantation site, to the first supra-pubic incision I_{S1}. The length of the first arm **512** of the sling **510**, however, is shorter than the length of the dilator **100**. As a result, the first arm **512** of the sling **510** remains within the lumen of the dilator **100** while at least the first portion of the suture **522** extends through the distal opening **107** of the dilator **100** and outside of the body B. In some embodiments, however, the first arm **512** of the sling **510** can have any suitable length. For example, in some embodiments, the length of the first arm **512** of the sling **510** can be greater than the length of the dilator **100** such that a portion of the first arm **512** can extend through the distal opening **107** of dilator and/or outside of the body B.

Returning to the flow chart shown in FIG. **4**, the dilator is removed from the body tissue by moving the dilator in the first direction, **453**. As shown in FIG. **8**, the dilator **100** is removed from the body B by moving the dilator **100** in the distal direction AA. In this manner, the dilator **100** is inserted into the body B and removed from the body B in the same direction. Thus, the dilator **100** enters the body B via the vaginal incision I_V and exits the body B via the first supra-pubic incision I_{S1}.

As shown in FIG. **8**, the sling **510** remains within the body B after the dilator **100** is removed from the body B. Thus, the sling **510** is in contact with the body tissue between the first supra-pubic incision I_{S1} and the first layer tissue incision I_T after the dilator **100** is removed from the body B. In some embodiments, the sling **510** can be configured to promote tissue ingrowth in the surrounding bodily tissue (e.g., the tissue between the first supra-pubic incision and the first layer tissue incision I_T and/or the tissue of the organ) alter the dilator **100** is removed and the sling **510** is placed in contact with the tissue of body B.

The sling **510** maintains a substantially constant position within the body B when the dilator **100** is removed.

Once the dilator **100** is removed from the body B, the sutures **522** and/or **523** can be trimmed off or otherwise removed from the respective arms **512** and/or **513** of the sling **510**. The sling **510** itself can also be trimmed after the dilator **100** is removed form the body B. Additionally, the vaginal incision I_V, the first tissue layer incision I_T (or any other internal incisions), and/or each of the supra-pubic incisions I_{S1} and I_{S2} can be closed via any suitable manner.

Although the sling **510** is illustrated and described above as being coupled to sutures **522** and **523**, in other embodiments, the sling **510** is not coupled to sutures. In such embodiments, the first arm **512** of the sling **510** can be passed through the lumen defined by the dilator **100** via, a pusher or like device. Similarly, the second arm **513** of the sling **510** can be passed through the lumen defined by the dilator **500** via a pusher or like device. In some embodiments, the sling **510** is attached to only one of the sutures **522** or **523**.

FIG. **9** is a schematic illustration of a dilator assembly, which includes dilators **600** and **700** coupled to an implant **610**. The dilators **600** and **700** are configured to be inserted within a body of a patient and to deliver the implant **610** within the body. The term "implant" will be referred to herein as a "sling" in the same manner discussed above with reference to implant **510** (i.e., sling **510**). The dilator **600** includes a proximal end portion **603** having an enlarged portion **606**, and a distal end portion **602** having a tapered tip **605**. Additionally, the dilator **600** defines a distal opening **607**, a proximal opening **608**, an aperture **609** and a lumen (not identified) extending therethrough. The dilator **600** has substantially the same structure and operation as dilator **100**, but includes an aperture **609** in the distal end portion **602** of the dilator **600**. Thus, the proximal end portion **603**, the distal end portion **602**, the enlarged portion **606**, and the tapered tip **605** have substantially the same structure and operation as the proximal end portion **103**, the distal end

portion **102**, the enlarged portion **106**, and the tapered tip **105** of the dilator **100**, and are, therefore, not described in detail herein unless otherwise specified. Additionally, the distal opening **607**, the proximal opening **608**, and the lumen have substantially the same structure and operation as the distal opening **107**, the proximal opening **108**, and the lumen defined by the dilator **100**, and are, therefore, not described in detail herein unless otherwise specified. Furthermore, the dilator **700** has substantially the same structure and operation as dilator **600** and thus, will not be described in detail herein unless otherwise specified.

The aperture **609** is located in the distal end portion **602** of the dilator **600**. The aperture **609** is configured to receive a portion of a first suture **622**, as described in more detail herein. The aperture **609** can have any suitable shape and/or size. For example, although the aperture **609** is illustrated in FIG. **9** as having a substantially circular shape, in other embodiments, the aperture **609** can have, for example, an oval shape, a square shape, a star shape and/or the like. Additionally, the aperture **609** can be formed by any suitable process, such as, for example, molding, drilling, casting, or the like.

The sling **610** is operatively coupled to the dilators **600** and **700** via sutures **622** and **623**, respectively. The sling **610** is configured to be implanted within the body to support a desired tissue or organ within the body. The sling **610**, which is illustrated in FIG. **9** as a flat mesh tape, includes a first arm **612** and a second arm **613**. The first arm **612** is coupled to a second portion (not identified) of the first suture **622**, and the second arm **613** is coupled to a second portion (not identified) of the second suture **623**. As will be described in more detail herein, the first arm **612** is configured to be implanted within the body via the dilator **600** and the second arm **613** is configured to be implanted within the body via the dilator **700**. The arms **612** and **613** are configured to be received within the lumens of the dilators **600** and **700**, respectively.

As shown in FIG. **9**, the first suture **622** is disposed within at least a portion of the lumen defined by the dilator **600** when the second portion of the first suture **622** is coupled to the first arm **612** of the sling **610**. The first suture **622** includes a first portion (not identified) that extends through the aperture **609** (i.e., from the inside-out) and is coupled to the distal end portion **602** of the dilator **600** via the aperture **609**. In some embodiments, the first portion of the first suture **622** can include a knot to prevent the first portion from receding back through the aperture **609**, which thereby couples the first suture **622** to the dilator **600**. The first portion of the first suture **622**, however, can include any suitable anchor to prevent the first portion from receding back through the aperture **609**. For example, in some embodiments, the first portion of the first suture **622** can be fixedly coupled within the aperture **609** via an adhesive.

The first portion of the first suture **622** can be coupled to the distal end portion **602** of the dilator **600** via the aperture **609** in any suitable manner. For example, in some embodiments, the first portion of the first suture **622** can be pulled through the distal opening **607** of the dilator **600** and then laced through the aperture **609** from the outside-in. A knot can be formed at the first portion of the first suture **622** to prevent the first suture **622** from receding back through the aperture **609**. In some embodiments, a portion of the exposed first suture **622** can further be formed into a loop (shown, for example, in FIGS. **11** and **12**). The surgeon, for example, can exert a force on the first suture **622** via the loop such that the knot (or other anchor) is forced through the aperture **609**, thereby uncoupling the first suture **622** from the dilator **600**. The loop can then be used to pull or move the first arm **612** of the sling **610** into the lumen of the dilator **600**, as described herein.

In some embodiments, a kit can include the dilators **600** and **700** and the implant **610**. In some such embodiments, the kit can be pre-assembled such that the implant **610** is coupled to the dilators **600** and **700** via sutures **622** and **623**, respectively. The implant **610** can be coupled to the dilators **600** and/or **700** in any manner described herein. In some embodiments, the sling **610** can be pre-formed into a roll and included in the kit. In this manner, the sting **610** can be inserted into the body in its pre-formed configuration and can, for example, unroll into its original configuration at some time during or after the implantation procedure.

FIG. **10** is a flow chart of a method **860** of inserting an implant **610** into a body B of a patient. The method illustrated in FIG. **10** is discussed with references FIGS. **11-15**, which are schematic illustrations of the implant **610** being inserted into the body B via the dilator assembly shown in FIG. **9**. The term "implant" will be referred to herein as a "sling," as discussed above. The method **860** includes extending a dilator through a body tissue of a patient such that a distal end portion of the dilator extends from the body tissue, **861**. Referring to FIGS. **11** and **12**, the dilator **600** extends through the body B (including internal body tissue) of the patient such that the distal end portion **602** of the dilator **600** extends from the body B. Similarly, the dilator **700** extends through the body B of the patient such that a distal end portion **702** of the dilator **700** extends from the body B. It should be understood that, during the procedures described herein, the dilator **700** performs the same steps or operations that dilator **600** performs. Therefore, when the dilator **600** is described as or referred to in performing a particular step or operation, it should be understood that dilator **700** is also involved in or performing that particular step or operation, unless otherwise specified.

The dilator **600** is inserted into the body B via a vaginal incision, I_V (shown in FIG. **12**). The dilator **700** is also inserted into the body B via the vaginal incision I_V. In this manner, there is only a single incision in the vaginal wall I_V through which both dilators **600** and **700** extend. In some embodiments, however, the dilators **600** and/or **700** are inserted into the body B via separate vaginal incisions. The incision I_V can be made at any location along the vaginal wall V depending on the intended implantation site of the sling **610** within the pelvic region, as described above. When the dilator **600** is extended through the body B, as shown in FIG. **12**, the proximal end portion **603** of the dilator **600** is disposed within at least the first layer of tissue T_1 (via, a first tissue layer incision I_T) in which the sling **510** is to be anchored and a proximal-most end (not identified) of the dilator **600** is flush with that first layer of tissue T_1 as described above.

As shown in FIG. **12**, the dilator **600** extends through an obturator membrane O_B within the body B when the distal end portion **602** of the dilator **600** extends through the body **13**. More particularly, the dilator **600** extends through a first obturator incision I_{OB1} when the distal end portion **602** of the dilator **600** extends from a first perineum incision I_{P1}. Similarly, the dilator **700** extends through the opposing obturator membrane (not illustrated) via a second obturator incision (not illustrated) when the distal end portion **702** of the dilator **700** ends from the body B via a second perineum incision I_{P2}. The first perineum incision I_{P1} and the obturator membrane O_B are located toward the right side of the body B, and the second perineum incision I_{P2} and opposing obturator membrane are located toward the left side of the

body B relative to the perspective of the patient. In some embodiments, however, the perineum incisions I_{P1} and I_{P2} can be made at any location in the perineum region of the body B. Similarly, the obturator incisions (e.g., the first obturator incision I_{OB1}) can be made at any location along the obturator membranes the obturator membrane O_B) The location of the perineum incisions I_{P1} and/or I_{P2} can depend, for example, on the intended implantation site of the sling **610** within the pelvic region.

The dilator **600** can be inserted into the body B using one of the methods described above with reference to FIGS. **2** and **3**. More particularly, the dilator **600** can be pushed through the body B using, for example, the delivery needle **230** (i.e., the "push" method). Or, the dilator **600** can be pulled through the body B using, for example, the delivery needle **330** (i.e., the "pull" method). In most instances, however, the "pull" method is regularly used for procedures involving perineum and/or obturator incisions. As such, the delivery needle (e.g., delivery needle **330**) is inserted and moved within the body B along a path that includes the first perineum incision I_{P1}, the first obturator incision I_{OB1}, the first tissue layer incision I_T (and any other internal body tissue incisions) and the vaginal incision I_V. Once the delivery needle reaches the vaginal incision I_V, the distal end portion **602** of the dilator **600** can be coupled to the delivery needle, in the manner described above, and inserted into the body B. The dilator **600** is inserted into the body B by being pulled in distal direction CC through the vaginal incision I_V, through the first tissue layer incision I_T, through the obturator incision I_{OB1}, and further through the first perineum incision I_{P1} until the distal end portion **602** of the dilator **600** extends through the first perineum incision I_{P1}. In some embodiments, the dilator **700** can be inserted into the body B in a manner different from the dilator **600**, as discussed above.

The dilators **600** and **700** are inserted into the body B in a similar configuration to that shown in FIG. **9**. Similar to the configuration shown in FIG. **9**, the sling **610** is operatively coupled to the dilators **600** and **700** via sutures **622** and **623** when the dilators **600** and **700** are inserted within the body B. The sutures **622** and **623** shown in FIGS. **11** and **12**, however, are in a looped configuration. More specifically, with respect to dilator **600**, the first portion of the first suture **622** extends through the lumen and out from the distal opening **607**, then loops around the outside of the dilator **600** and through the aperture **609**. The first portion of the first suture **622** disposed through the aperture **609** is then securely fastened to the dilator **600**, for example, via a knot, as described above. A loop (not identified) is then formed with the portion of the first suture **622** disposed outside of the dilator **600**. During this phase of the implantation procedure, the sling **610** remains outside of the body B.

Returning to the flow chart shown in FIG. **10**, the first portion of the suture is uncoupled from the distal end portion of the dilator, **862**. As shown in FIG. **13**, the first portion of the first suture **622** is uncoupled from the distal end portion **602** of the dilator **600** when the first suture **622** is moved in direction CC. A surgeon, for example, can pull the first suture **622** (e.g., via the loop) such that the force exerted on the first suture **622** in the distal direction CC forces the knot through the aperture **609** and, thereby uncouples the first suture **622** from the distal end portion **602** of the dilator **600**. In some embodiments, however, the first portion of the first suture **622** is uncoupled from distal end portion **602** of the dilator **600** in any suitable manner, such as, for example, via severing.

Returning to the flow chart shown in FIG. **10**, at least a portion of an implant is passed through the lumen defined by the dilator by pulling on the first portion of the suture, **863**. As shown in FIG. **14**, the first arm **612** of the sling **610** is passed or moved through the lumen defined by the dilator **600** by pulling the first portion of the first suture **622** in distal direction CC. For example, once the first suture **622** is uncoupled from the distal end portion **602** of the dilator **600**, the surgeon, for example, can continue to pull the first suture **622** (e.g., via the loop) in the distal direction CC until the first arm **612** of the sling **610** is pulled into the lumen of the dilator **600**. In some embodiments, the acts of pulling the first portion of the first suture **622** to uncouple it from the dilator **600** and to pull the sling **610** into the dilator **600** is performed in a continuous motion. In some embodiments, the first suture **622** can continue to be pulled until the first arm **612** of the sling **610** is in the desired position within the lumen defined by the dilator **600**. As described above, the desired position of the first aim **612** of the sling **610** within the lumen can, for example, correspond to the desired location of the sling **610** within the body B after implantation. Such a desired position can be achieved by, for example, adjusting and/or tensioning the first arm **612** of the sling **610** within the lumen relative to the second arm **613**.

As shown in FIG. **14** and described above, when the first arm **612** is disposed within the lumen of the dilator **600**, the dilator **600** is configured to act a barrier between the first arm **612** of the sling **610**, the obturator membrane O_B and the body B (including any bodily tissue other that the tissue or organ it is intended to support). The first arm **612** of the sting **610** has a length sufficient to extend through body tissue from the vaginal incision I_V or the desired implantation site, to the first perineum incision I_{P1}. The length of the first arm **612** of the sling **610**, however, is shorter than the length of the dilator **600**. As a result, the first arm **612** of the sling **610** remains within the lumen of the dilator **600** while at least the first portion of the first suture **622** extends through the distal opening **607** of the dilator **600** and outside of the body B, as described above. In some embodiments, however, the first aim **612** of the sling **610** can have any suitable length, as described above. For example, in some embodiments, the length of the first arm **612** is only sufficient to extend from the vaginal incision I_V or the desired implantation site, to the first obturator incision I_{OB1}.

Returning to the flow chart shown in FIG. **10**, the dilator is removed from the body tissue through a skin incision, **864**. As shown in FIG. **15**, the dilator **600** is removed from the body B through the first perineum incision I_{P1}. In this manner, the dilator **600** is inserted into the body B and removed from the body B in the same direction (i.e., distal direction CC). Thus, the dilator **600** enters the body B via, the vaginal incision I_V and exits the body B via the first perineum incision I_{P1}. In some embodiments, however, the dilator **600** can be removed from the body B through the vaginal incision I_V. In this manner, the dilator **600** is inserted and removed from the same incision.

As shown in FIG. **15**, the sting **610** remains within the body B after the dilator **600** is removed from the body B, as described above. Thus, the sling **610** is in contact with the body tissue between the first layer tissue incision I_T and the first perineum incision I_{P1} (including the obturator membrane O_B) after the dilator **600** is removed from the body B. In some embodiments, the sting **610** can be configured to promote tissue ingrowth in the surrounding bodily tissue, including the obturator membrane O_B, after the dilator **600** is removed and the sling **610** is placed in contact with the body B.

Once the dilators **600** and **700** are removed from the body B, the sutures **622** and/or **623** can be trimmed off or otherwise removed from the respective arms **612** and/or **613** of the sting **610**. The sling **610** itself can also be trimmed off after the dilators **600** and **700** are removed form the body B. Additionally, the vaginal incision I_V, the first layer tissue incision I_T, the obturator incision I_{OB1} and/or each of the perineum incisions I_{P1} and I_{P2} can be closed via any suitable manner.

Although the sling **610** is illustrated and described above as being coupled to sutures **622** and **623**, in other embodiments, the sling **610** is not coupled to sutures. In such embodiments, the first arm **612** of the sling **610** can be passed through the lumen defined by the dilator **600** via a pusher or like device. Similarly, the second arm **613** of the sling **610** can be passed through the lumen defined by the dilator **600** via a pusher or like device. In some embodiments, the sling **610** is attached to only one of the sutures **622** or **623**.

While various embodiments of the invention have been described above, it should be understood that they have been presented by way of example only, and not limitation. Thus, the breadth and scope of the invention should not be limited by any of the above-described embodiments, but should be defined only in accordance with the following claims and their equivalents. While the invention has been particularly shown and described with reference to specific embodiments thereof, it will be understood that various changes in form and details may be made.

Although the dilators illustrated and described above were used to delivery or implant an implant into a pelvic region via a specific approach, in other embodiments, the dilator(s) can be used to deliver or implant an implant into a pelvic region using a variety of different approaches, including for example, a transvaginal approach, a retropubic approach, a supra pubic approach, or a transobturator approach.

Although the dilators are illustrated and described above as being positioned within the body such that the proximal end portion of the dilators are disposed within the vaginal area and the distal end portion of the dilators are disposed adjacent the outer surface of the body, in other embodiments, a dilator is positioned within the body in the opposite configuration. For example, the dilator can be positioned within the body such that the distal end portion of the dilator is disposed within the vaginal area and the proximal end portion of the dilator is disposed adjacent the outer surface of the body. In some such embodiments, a suture coupled to an implant, or the implant itself, is pulled into the lumen of the dilator via the distal opening. In this manner, the suture and/or the implant moves or passes through the lumen of the dilator in the opposite direction to that described above (i.e., from the distal end portion of the lumen to the proximal end portion of the lumen). The suture and/or the implant can be moved through the lumen by any of the means described above. For example, in some embodiments, the suture and/or the implant is coupled to a delivery needle (e.g., delivery needle **230** or **330**) and pulled through the lumen.

Although the dilators and procedures are illustrated and described above with reference to a female pelvic region, it should be understood that the same dilators and/or procedures can be used in the male pelvic region without substantial modification. For example, where the female pelvic region is accessed via a vaginal incision in the aforementioned procedures, the male pelvic region can be accessed via right and left perineum incisions. In some embodiments, the female pelvic region can be accessed via perineum incisions rather than a vaginal incision in the aforementioned procedures.

The implant(s) described herein can be formed with a variety of different materials, such as biocompatible plastics and/or metals. In some embodiments, the implant is formed at least in part with a mesh material to promote tissue in-growth. An implant can also be formed fully or in part with biological or natural materials or combinations of biological and synthetic materials. An implant can be formed at least in part with, for example, the Advantage® Mesh by Boston Scientific Corporation. Alternatively, the implant can be formed with Polyform® Synthetic Mesh material by Boston Scientific Corporation.

The implant(s) can have a variety of different configurations and/or different sizes (e.g. lengths, widths), depending on the intended use for the particular implant and the intended implantation site for the implant within the pelvic region.

The previous description of the embodiments is provided to enable any person skilled in the art to make or use the invention. While the invention has been particularly shown and described with reference to embodiments thereof, it will be understood by those skilled in art that various changes in form and details may be made. For example, a dilator can include various combinations and sub-combinations of the various embodiments described herein.

In some embodiments, a method includes extending a dilator into a body tissue of a patient in a first direction such that a distal end portion of the dilator extends from the body of the patient. The dilator defines a lumen therethrough. At least a portion of the dilator is disposed within the body tissue when the distal end portion extends from the body. At least a portion of an implant is passed through the lumen defined by the dilator. The dilator is removed from the body tissue by moving the dilator in the first direction.

In some embodiments, the dilator can be extended by pushing the distal end portion of the dilator through the body tissue.

In some embodiments, the dilator can be extended by pulling the distal end portion of the dilator through the body tissue.

In some embodiments, the dilator can be extended into a portion of the body tissue in a pelvic region of the patient.

In some embodiments, the dilator can be extended such that a proximal end of the dilator is aligned with a surface of the body tissue. In this manner, the proximal end is flush with the surface.

In some embodiments, the distal end portion of the dilator can be configured to contact a portion of a delivery needle when the dilator is being extended into the body tissue.

In some embodiments, the dilator can be extended into the body tissue via a first incision, and is removed from the body via a second incision.

In some embodiments, the portion of the implant can be passed through the lumen by pushing the portion of the implant through the lumen in the first direction.

In some embodiments, the portion of the implant can be passed through the lumen by pulling the portion of the implant through the lumen in the first direction.

In some embodiments, the portion of the implant can be passed through the lumen in a second direction opposite the first direction.

In some embodiments, the first direction can be a distal direction.

In some embodiments, a proximal end portion of the dilator can include an enlarged portion, which is in fluid

communication with the lumen. In some such embodiments, the enlarged portion can be configured to facilitate the passing of the portion of the implant through the lumen.

In some embodiments, the implant can be configured to be used to treat male incontinence.

In some embodiments, a method includes extending a dilator into body tissue of a patient such that a distal end portion of the dilator extends from the body of the patient. The distal end portion of the dilator is coupled to a first portion of a suture such that the first portion of the suture is disposed outside of the body when the distal end portion of the dilator extends from the body. The suture has a second portion coupled to an implant. The dilator defines a lumen therethrough. The first portion of the suture is uncoupled from the distal end portion of the dilator and at least a portion of the implant is passed through the lumen defined by the dilator by pulling on the first portion of the suture. The dilator is removed from the body tissue through a skin incision.

In some embodiments, the method can also include coupling the first portion of the suture to the distal end portion of the dilator. In some such embodiments, the distal end portion of the dilator can define an aperture through which the first portion of the suture is disposed.

In some embodiments, after the dilator is removed from the body tissue, the method can also include, trimming the portion of the implant that extends from the bodily tissue such that the suture is detached from the implant.

In some embodiments, the dilator can be extended into a body tissue in a pelvic region of the patient.

In some embodiments, the dilator can be extended into the body tissue in a first direction, and can be removed from the body tissue in a direction substantially the same as the first direction.

In some embodiments, the dilator can be extended into the body tissue in a first direction, and can be removed from the body tissue in a second direction substantially opposite the first direction.

In some embodiments, the dilator can be extended into the body tissue and through a portion of an obturator.

In some embodiments, the distal end portion of the dilator can be configured to contact a portion of a delivery needle when the dilator is being extended into the body tissue.

In some embodiments, the suture can be uncoupled by pulling on a loop formed by the first portion of the suture such that the first portion of the suture uncouples from the distal end portion of the dilator.

In some embodiments, the incision can be one of a supra-pelvic incision, a retro-pubic incision, or a perineum incision.

In some embodiments, the implant can be configured to be used to treat male incontinence.

In some embodiments, the implant can be a mesh implant.

What is claimed is:

1. A method, comprising:

inserting a needle of a delivery needle into a lumen of a first dilator, wherein, when the needle is inserted into the lumen of the first dilator, a tip of the needle extends outside the lumen from a first opening of the first dilator;

extending the first dilator into a body of a patient via a vaginal incision in a direction until a distal end portion of the first dilator extends from a first supra-pubic incision, the first dilator defining the first opening disposed proximate the distal end portion and a second opening disposed proximate to a proximal end portion of the first dilator, the lumen of the first dilator extending from the first opening to the second opening, at least a portion of the first dilator being disposed within the body when the distal end portion extends from the body, wherein a first suture extends through at least a portion of the lumen of the first dilator, the first suture having a first end portion coupled to an implant;

passing, after the extending, a first portion of the implant through the vaginal incision and then into the lumen defined by the first dilator by pulling on a second end portion of the first suture;

removing the first dilator from the body via the first supra-pubic incision by moving the first dilator in a direction that is the same as the direction used to extend the first dilator into the body of the patient while the portion of the first portion of the implant slides out of the lumen defined by the first dilator and remains in the body, wherein the removing includes removing the needle of the delivery needle from the body of the patient via the vaginal incision and removing the first dilator from the body of the patient via the first supra-pubic incision;

extending a second dilator into the body of the patient via the vaginal incision until a distal end portion of the second dilator extends from a second supra-pubic incision,

wherein a second suture extends through at least a portion of the lumen of the second dilator, the second suture having a first end portion coupled to a second portion of the implant, the first dilator and the second dilator extending into the body of the patient via the same vaginal incision;

passing, after the extending, the second portion of the implant through the vaginal incision and then into the lumen defined by the second dilator.

2. The method of claim **1**, wherein the extending includes pushing the distal end portion of the first dilator through the body.

3. The method of claim **1**, wherein the extending includes pulling the distal end portion of the first dilator through the body.

4. The method of claim **1**, wherein the extending includes extending the first dilator into a portion of the body in a pelvic region of the patient.

5. The method of claim **1**, wherein the extending includes aligning the proximal end portion of the first dilator with a surface of the body such that the proximal end portion is flush with the surface.

6. The method of claim **1**, wherein, during the extending, the distal end portion of the first dilator is configured to contact a portion of the delivery needle.

7. The method of claim **1**, wherein the passing includes pushing the portion of the implant through the lumen of the first dilator in a direction that is the same as the direction used to extend the first dilator into the body of the patient.

8. The method of claim **1**, wherein the passing includes pulling the portion of the implant through the lumen of the first dilator in a direction that is the same as the direction used to extend the first dilator into the body of the patient.

9. The method of claim **1**, wherein the direction used to extend the first dilator into the body of the patient is a distal direction.

10. The method of claim **1**, wherein the proximal end portion of the first dilator includes an enlarged portion in fluid communication with the lumen of the first dilator, the enlarged portion configured to facilitate the passing.

11. A method, comprising:

inserting a needle of a delivery needle into a lumen of a dilator, the delivery needle also including a handle extending the needle, the dilator defining a first opening at a distal end portion of the dilator and a second opening at a proximal end portion of the dilator such that the lumen extends from the first opening to the second opening, wherein, when the needle is inserted into the lumen of the dilator, a tip of the needle extends outside the lumen from the first opening of the dilator;

pushing the needle and the dilator into a body of a patient via a vaginal incision until the distal end portion of the dilator extends from a supra-pubic incision, the distal end portion of the dilator being coupled to a first portion of a suture such that the first portion of the suture is disposed within the body when the distal end portion of the dilator extends from the body via the supra-pubic incision, the suture having a second portion coupled to an end portion of an implant, the distal end portion of the dilator defining an aperture proximate to the first opening, the suture extending through the aperture;

uncoupling the first portion of the suture from the distal end portion of the dilator;

passing, after the extending, at least a portion of the implant through the vaginal incision and then into the lumen defined by the dilator by pulling on the first portion of the suture and moving the suture through the aperture;

removing the needle of the delivery needle from the body of the patient through the vaginal incision; and

removing the dilator from the body of the patient through the supra-pubic incision.

12. The method of claim 11, further comprising:

coupling the first portion of the suture to the distal end portion of the dilator, the distal end portion of the dilator defining the aperture through which the first portion of the suture is disposed.

13. The method of claim 11, further comprising:

after the removing, trimming the portion of the implant extending through the bodily tissue such that the suture is detached from the implant.

14. The method of claim 11, wherein the pushing includes pushing the dilator into a portion of the body in a pelvic region of the patient.

15. The method of claim 11, wherein the pushing includes pushing the needle and the dilator into the body in a direction towards the supra-pubic incision, and the removing includes removing the dilator from the body via the supra-pubic incision by moving the dilator in a direction substantially the same as the direction used to push the dilator into the body.

16. The method of claim 11, wherein the pushing includes pushing the dilator into the body and through a portion of an obturator.

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